



## Progenics Pharmaceuticals Announces Second Quarter 2019 Financial Results and Business Update

August 9, 2019

- Recorded First Revenues for AZEDRA®; CMS Grants New Technology Add-On Payment of Up to \$98,150 per Therapeutic Dose for Inpatient Use of AZEDRA
- Enrollment Completed Ahead of Schedule in Phase 3 CONDOR Trial of PyL™ (<sup>18</sup>F-DCFPyL); Topline Data Expected by Year End 2019
- First Patient Dosed in Phase 2 Trial of 1095

NEW YORK, Aug. 09, 2019 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) today announced financial results for the second quarter 2019 and provided a business update.

"We are excited to report significant progress across our entire portfolio, with commercial, clinical, and business development achievements forming a strong foundation for near-term growth," said Mark Baker, Chief Executive Officer of Progenics. "AZEDRA commercial dosing is underway and we are now focused on converting our growing number of treatment requests into treated patients. We are on our way to unlocking the significant value of this drug for both patients and our shareholders."

Mr. Baker continued, "We also continued to drive the development of our PSMA-targeted prostate cancer pipeline of diagnostics and therapeutics. Strong interest in our PyL imaging agent resulted in rapid enrollment in our Phase 3 CONDOR study, and we are now looking ahead to a topline data readout by year end. We commenced dosing in our Phase 2 trial of 1095 and, assuming early positive data from this open-label trial, see potential to advance 1095 into a pivotal trial in 2020 following agreement from the FDA. Our recent partnerships with ROTOP and FUJIFILM, together with our established partnerships with Bayer and Curium, provide additional validation for our PSMA-targeted approach and expand the reach of our pipeline across the globe. As we continue to grow our pipeline and operations, we remain focused on delivering our life-saving treatments for cancer to the patients who need them while creating significant value for our shareholders."

### Second Quarter and Recent Key Business Highlights

*AZEDRA (iobenguane I 131) 555 MBq/mL injection for intravenous use, Ultra-orphan Radiotherapeutic*

- **U.S. Launch of AZEDRA Advances with First Patients Dosed**  
AZEDRA is the first and only approved therapy in the U.S. for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. In June 2019, the Company recorded its first commercial sales and completed the first administrations of commercial AZEDRA. As of today, there are 13 multidisciplinary treatment centers across the U.S. activated for patient treatment. We have 32 treatment requests. Our commercial focus is on converting these requests to treated patients.
- **CMS Grants New Technology Add-On Payment for Inpatient Use of AZEDRA**  
Last week, Centers for Medicare & Medicaid Services (CMS) approved a new technology add-on payment (NTAP) for AZEDRA when administered in the hospital inpatient setting for Medicare beneficiaries in FY2020. The NTAP will cover the lesser of 65 percent of the average cost of AZEDRA, or 65 percent of the costs in excess of the Medicare Severity Diagnosis Related Groups (MS-DRG) payment for the case. As a result, the maximum NTAP for a case involving a therapeutic dose of AZEDRA is \$98,150.
- **Initiation of Basket Trial by Year End to Support Expanded Label**  
The Company reached alignment with the U.S. Food and Drug Administration (FDA) on a clinical development plan to potentially support an expanded label for AZEDRA for the treatment of patients with advanced neuroendocrine tumors (NETs) who have MIBG-avid tumors. Progenics plans to conduct a tissue agnostic, basket study that will evaluate AZEDRA in patients with NETs that are MIBG-avid, including gastroenteropancreatic neuroendocrine tumors, as well as other NETs, and utilize a dosing regimen that enables outpatient administration. The basket study is expected to begin by the end of the year and enroll approximately 150 patients at sites in the U.S and Canada.
- **Updated Survival Data Presented at ASCO**  
Long-term follow up data from the pivotal Phase 2 study of AZEDRA were presented at the 2019 American Society of Clinical Oncology (ASCO) 2019 Annual Meeting. Notably, data showed a five-year long-term survival rate of 38.3% and a median survival time for all patients of 41.1 months (95% CI 31.1, 91.2).

*PSMA-Targeted Prostate Cancer Pipeline*

- **Enrollment Completed Ahead of Schedule in Phase 3 Trial of PyL (<sup>18</sup>F-DCFPyL); Topline Data Expected by Year**

## End 2019

Patient enrollment for the Phase 3 CONDOR trial, evaluating the diagnostic performance and clinical impact of PyL was completed five months ahead of schedule. The Phase 3 CONDOR trial is a multi-center, open label trial that enrolled 208 male patients with biochemical recurrence of prostate cancer at 14 sites in the U.S. and Canada. Based on discussions with the FDA, Progenics believes that positive data from the CONDOR study and the previously reported OSPREY study could serve as the basis for a New Drug Application for PyL.

- **Multiple Data Presentations at SNMMI 2019 Annual Meeting Highlight Potential of PyL**

Data from the Company's Phase 2/3 OSPREY trial of PyL in men with high risk and metastatic prostate cancer and three investigator-sponsored studies conducted under the Company's PyL Research Access Program™ that evaluated PyL in men with biochemically recurrent prostate cancer were presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2019 Annual Meeting. The data presented highlighted the high diagnostic potential of PyL to detect high risk primary prostate cancer, biochemically recurrent prostate cancer, and metastatic disease, as well as importantly alter physician treatment decision-making.

- **Initiation of Patient Dosing in Phase 2 Trial of 1095**

The Company announced that the first patient was dosed in the ongoing Phase 2 trial of 1095 in combination with enzalutamide in chemotherapy-naïve patients with metastatic castration-resistant prostate cancer (mCRPC). 1095 is a small molecule radiotherapeutic designed to selectively bind to the extracellular domain of prostate specific membrane antigen (PSMA), a protein that is highly expressed on prostate cancer cells. Based on the early data emerging from this open-label trial and dialogue with the FDA, the Company plans to evaluate initiating a pivotal trial of 1095 in 2020.

- **Partner Bayer Initiates Phase 1 Trial of PSMA TTC, Triggering \$2.0 Million Milestone Payment**

Bayer dosed the first patient in its Phase 1 trial of PSMA TTC, a PSMA-targeted monoclonal antibody thorium conjugate in the development for the treatment of metastatic castration resistant prostate cancer. Under the terms of the companies' 2016 collaboration, the achievement of this clinical milestone triggered a \$2.0 million payment to Progenics.

- **Progenics Pharmaceuticals Provides Update on PSMA-617 Intellectual Property Ownership Assertion**

On August 6, the District Court of Mannheim in Germany held the first oral hearing in the case. The Court considered procedural matters and granted the parties the right to make further submissions.

- **European Collaboration with ROTOP for 1404**

The Company entered into an exclusive license agreement with ROTOP Pharmaka GmbH (ROTOP), a leading radiopharmaceuticals company focused on diagnostics and therapeutics, to develop and commercialize 1404 in Europe. Under the terms of the collaboration, ROTOP will be responsible for the development, regulatory approvals, and commercialization of 1404 in Europe, while Progenics is entitled to double-digit, tiered royalties on net sales in the territory. ROTOP plans to request a meeting with European regulators to discuss a clinical development plan for 1404 and start a clinical trial in early 2020.

## Digital Technology

- **FDA 510(k) Clearance Granted for Cloud-Based Version of Automated Bone Scan Index (aBSI)**

The aBSI automatically segments the anatomical regions of the skeleton and detects and classifies lesions in the bone scan of prostate cancer patients. The aBSI has been shown to be an objective measure of the quantitative change in disease burden and is a prognostic biomarker in patients with metastatic prostate cancer. Earlier this week, the Company received 510(k) clearance from the FDA to market its cloud-based version of aBSI product in the U.S. This clearance of our cloud-based software as a medical device is an essential step towards the further development of PSMA AI.

- **Validating PSMA AI Data Presented at SNMMI**

The Company presented results from its PSMA AI technology at the SNMMI 2019 Annual Meeting during an oral session. The prospective study evaluated the diagnostic performance of PSMA AI using SPECT/CT scans from the Company's Phase 3 study of 1404. Independent readers using Progenics' PSMA AI demonstrated a statistically significant improvement of accuracy, speed, and reproducibility over readers without PSMA AI.

- **Collaboration with VA on Progenics' AI Research Plan**

Progenics initiated a collaboration that provides the VA Greater Los Angeles Healthcare System (VAGLAHS) with access to the Company's AI platform for investigational use. In the project, the VAGLAHS network will gain access to Progenics' machine learning platforms, which includes the aBSI and the PSMA AI platforms. The collaboration will explore novel predictive machine learning algorithms from the digital medical images and associated clinical outcomes. These novel algorithms will be prospectively validated at VAGLAHS for effective healthcare management of veterans with prostate cancer. This project is the nation's first collaborative effort to validate cutting-edge machine learning tools for improving

treatment management of veterans with prostate cancer and provides additional validation to Progenics' AI platform.

- **FUJIFILM Toyama Chemical Co. Acquires Japanese Rights to aBSI**

Progenics entered into a transfer agreement with FUJIFILM Toyama Chemical Co, Ltd. (FUJIFILM) for the rights to the Company's aBSI product in Japan for use under the name BONENAVI<sup>®</sup>. Under the terms of the agreement, FUJIFILM acquired, by a combination of purchase and license, the Japanese software, source code, supporting data, and all Japanese patents associated with the aBSI product from Progenics for use in Japan. In exchange, Progenics received \$4.0 million in an upfront payment and will receive service fees for aBSI and other AI products over three years in Japan. BONENAVI has been licensed to FUJIFILM for use in Japan since 2011.

*RELISTOR, Treatment for Opioid-Induced Constipation (partnered with Bausch Health Companies Inc.)*

- **Second Quarter 2019 RELISTOR Net Sales of \$24.0 Million**

The second quarter 2019 net sales of RELISTOR, as reported by its partner Bausch Health Companies, Inc., translated to \$3.6 million in royalty revenue for Progenics for the quarter.

- **RELISTOR Tablets Protected Until 2031 Following Federal Court Patent Decision**

U.S. District Court of New Jersey upheld the validity and determined Actavis' infringement of a patent protecting RELISTOR tablets, expiring March 2031. Defendant, Actavis Laboratories FL, Inc., a subsidiary of Teva Pharmaceutical Industries Ltd, had challenged the validity of and had alleged non-infringement of Claims 2 and 5 of U.S. Patent No. 8,524,276, which protects the formulation of RELISTOR tablets.

*Corporate Update*

- **Appointment of Huw Jones as Vice President, Commercial**

On July 8, 2019, Progenics appointed Huw Jones to the newly created role of Vice President, Commercial. Mr. Jones joins Progenics following several years on the commercial strategy and operations team at Novartis Pharmaceuticals, as well as its subsidiaries, Advanced Accelerator Applications SA and Novartis Oncology. In his two decades at Novartis and its subsidiaries, Mr. Jones held various global leadership roles, including Executive Director and Global Brand Leader, Head of Global Commercial Excellence, as well as positions of increasing responsibility in general management, sales, marketing, training, and commercial operations.

## **Second Quarter 2019 Financial Results**

Second quarter revenue totaled \$10.0 million, up from \$3.9 million in the second quarter of 2018, primarily due to the achievement of a \$2.0 million milestone under the Bayer agreement for initiation of a Phase 1 trial of PSMA TTC and a \$4.0 million upfront payment from FUJIFILM under the aBSI transfer agreement.

Second quarter research and development expenses increased by \$3.7 million compared to the corresponding prior year period, primarily resulting from higher clinical trial costs and contract manufacturing costs for clinical trial materials for 1095 and PyL, as well as higher costs associated with the transition costs for the AZEDRA manufacturing site and additional production capacity for iodine-based products. Second quarter selling, general and administrative expenses increased by \$7.0 million compared to the corresponding prior year period, primarily due to increases in legal and advisory fees of \$5.5 million associated with the contested election at our 2019 Annual Meeting of Shareholders, PSMA-617 litigation costs of \$1.0 million, and costs associated with the build out of commercial infrastructure to support the launch and distribution of AZEDRA. Progenics also recorded non-cash adjustments of \$0.9 million in the second quarter 2019, related to changes in the fair value estimate of the contingent consideration liability. For the three months ended June 30, 2019, Progenics recognized interest expense of \$1.1 million related to the RELISTOR royalty-backed loan.

Net loss for the second quarter was \$19.7 million, or \$0.23 per diluted share, compared to net loss of \$15.2 million, or \$0.20 per diluted share, in the corresponding 2018 period.

Progenics ended the second quarter with cash and cash equivalents of \$84.8 million, a decrease of \$52.9 million compared to cash and cash equivalents as of December 31, 2018, reflecting primarily cash used for operating expenses and for the acquisition of the Somerset manufacturing site for the AZEDRA launch.

## **Conference Call and Webcast**

Progenics will review second quarter 2019 results in a conference call today at 8:30 a.m. EST. To participate, please dial (877) 250-8889 (domestic) or (720) 545-0001 (international) and reference conference ID 9149197. A live webcast will be available in the Media Center of the Progenics website, [www.progenics.com](http://www.progenics.com), and a replay will be available there for two weeks.

– Financial Tables Follow –

**PROGENICS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

For the Three Months Ended	For the Six Months Ended
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	<u>June 30,</u>		<u>June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenues:			(unaudited)	
AZEDRA product sales	\$ 270	\$ -	\$ 270	\$ -
Royalty income	3,593	3,530	7,754	6,588
License and other revenue	6,103	348	6,223	479
Total revenues	<u>9,966</u>	<u>3,878</u>	<u>14,247</u>	<u>7,067</u>
Operating expenses:				
Cost of goods sold	493	-	493	-
Research and development	13,080	9,347	25,472	17,457
Selling, general and administrative <sup>(1)</sup>	14,570	7,569	23,794	14,266
Change in contingent consideration liability	916	1,300	1,816	2,100
Total operating expenses	<u>29,059</u>	<u>18,216</u>	<u>51,575</u>	<u>33,823</u>
Operating loss	(19,093)	(14,338)	(37,328)	(26,756)
Other (expense) income:				
Interest (expense) income, net	(607)	(930)	(1,107)	(1,936)
Total other (expense) income	<u>(607)</u>	<u>(930)</u>	<u>(1,107)</u>	<u>(1,936)</u>
Loss before income tax benefit	<u>(19,700)</u>	<u>(15,268)</u>	<u>(38,435)</u>	<u>(28,692)</u>
Income tax benefit	-	96	-	96
<b>Net loss</b>	<u><b>\$ (19,700)</b></u>	<u><b>\$ (15,172)</b></u>	<u><b>\$ (38,435)</b></u>	<u><b>\$ (28,596)</b></u>
<b>Net loss per share - basic and diluted</b>	<u><b>\$ (0.23)</b></u>	<u><b>\$ (0.20)</b></u>	<u><b>\$ (0.45)</b></u>	<u><b>\$ (0.39)</b></u>
<b>Weighted average shares outstanding – basic and diluted</b>	<u><b>85,000</b></u>	<u><b>74,017</b></u>	<u><b>84,772</b></u>	<u><b>73,271</b></u>

(1) Included in the selling, general and administrative expenses for the three and six months ended June 30, 2019 are \$5.5 million and \$5.9 million, respectively of legal and advisory fees associated with the contested election at our 2019 Annual Meeting of Shareholders and \$1.0 million and \$1.8 million, respectively associated with PSMA-617 litigation.

**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)

	<u>June 30,</u>	<u>December</u>
	<u>2019</u>	<u>31,</u>
	(unaudited)	<u>2018</u>
		(audited)
Cash and cash equivalents	\$ 84,823	\$ 137,686
Accounts receivable, net	10,569	3,803
Property and equipment, net	7,008	3,944
Intangible assets, net and goodwill	25,222	19,740
Operating right-of-use lease assets	13,889	-
Other assets	11,270	4,324
<b>Total assets</b>	<u><b>\$ 152,781</b></u>	<u><b>\$ 169,497</b></u>
Current liabilities	\$ 23,571	\$ 23,446
Contingent consideration liability	4,800	3,950
Operating lease liability	15,312	-
Long-term debt, deferred tax and other liabilities	36,370	41,026
Total liabilities	<u>80,053</u>	<u>68,422</u>
Total stockholders' equity	<u>72,728</u>	<u>101,075</u>

**Indication**

AZEDRA® (iobenguane I 131) is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

**Important Safety Information****Warnings and Precautions:**

- **Risk from Radiation Exposure:** AZEDRA contributes to a patient's overall long-term radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. These risks of radiation associated with the use of AZEDRA are greater in pediatric patients than in adults. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with AZEDRA consistent with institutional good radiation safety practices and patient management procedures.
- **Myelosuppression:** Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia. Monitor blood cell counts weekly for up to 12 weeks or until levels return to baseline or the normal range. Withhold and dose reduce AZEDRA as recommended in the prescribing information based on severity of the cytopenia.
- **Secondary myelodysplastic syndrome, leukemia, and other malignancies:** Myelodysplastic syndrome (MDS) and acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years. Two of the 88 patients developed a non-hematological malignancy.
- **Hypothyroidism:** Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Initiate thyroid-blocking medications starting at least 1 day before and continuing for 10 days after each AZEDRA dose to reduce the risk of hypothyroidism or thyroid neoplasia. Evaluate for clinical evidence of hypothyroidism and measure thyroid-stimulating hormone (TSH) levels prior to initiating AZEDRA and annually thereafter.
- **Elevations in blood pressure:** Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension defined as an increase in systolic blood pressure to  $\geq 160$  mmHg with an increase of

20 mmHg or an increase in diastolic blood pressure to  $\geq 100$  mmHg with an increase of 10 mmHg. All changes in blood pressure occurred within the first 24 hours post infusion. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA.

- **Renal toxicity:** Of the 88 patients who received a therapeutic dose of AZEDRA, 9% developed renal failure or acute kidney injury and 22% demonstrated a clinically significant decrease in glomerular filtration rate (GFR) measured at 6 or 12 months. Monitor renal function during and after treatment with AZEDRA. Patients with baseline renal impairment may be at greater risk of toxicity; perform more frequent assessments of renal function in patients with mild or moderate impairment. AZEDRA has not been studied in patients with severe renal impairment.
- **Pneumonitis:** Fatal pneumonitis occurred 9 weeks after a single dose in one patient in the expanded access program. Monitor patients for signs and symptoms of pneumonitis and treat appropriately.
- **Embryo-fetal toxicity:** Based on its mechanism of action, AZEDRA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with AZEDRA and for 7 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the final dose.
- **Risk of infertility:** Radiation exposure associated with AZEDRA may cause infertility in males and females. Radiation absorbed by testes and ovaries from the recommended cumulative dose of AZEDRA is within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

**Adverse Reactions:**

The most common severe (Grade 3–4) adverse reactions observed in AZEDRA clinical trials ( $\geq 10\%$ ) were lymphopenia (78%), neutropenia (59%), thrombocytopenia (50%), fatigue (26%), anemia (24%), increased international normalized ratio (18%), nausea (16%), dizziness (13%), hypertension (11%), and vomiting (10%). Twelve percent of patients discontinued treatment due to adverse reactions (thrombocytopenia, anemia, lymphopenia, nausea and vomiting, multiple hematologic adverse reactions).

**Drug Interactions:**

Based on the mechanism of action of iobenguane, drugs that reduce catecholamine uptake or that deplete catecholamine stores may interfere with iobenguane uptake into cells and therefore interfere with dosimetry calculations or the efficacy of AZEDRA. These drugs were not permitted in clinical trials that assessed the safety and efficacy of AZEDRA. Discontinue the drugs listed in the prescribing information for at least 5 half-lives before administration of either the dosimetry dose or a therapeutic dose of AZEDRA. Do not administer these drugs until at least 7 days after each AZEDRA

dose.

**For important risk and use information about AZEDRA, please see Full Prescribing Information.**

**To report suspected adverse reactions, contact Progenics Pharmaceuticals, Inc. at 844-668-3950 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Reference:**

AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 08 2018 and 07 2018.

**About RELISTOR®**

Progenics has exclusively licensed development and commercialization rights for its first commercial product, RELISTOR, to Bausch Health Companies, Inc. RELISTOR Tablets (450 mg once daily) are approved in the United States for the treatment of opioid-induced constipation (OIC) in patients with chronic non-cancer pain. RELISTOR Subcutaneous Injection (12 mg and 8 mg) is a treatment for OIC approved in the United States and worldwide for patients with advanced illness and chronic non-cancer pain.

**IMPORTANT SAFETY INFORMATION - RELISTOR (methylnaltrexone bromide) tablets, for oral use and RELISTOR (methylnaltrexone bromide) injection, for subcutaneous use**

RELISTOR tablets and injection are contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their healthcare provider.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.

Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.

The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with mild renal impairment.

A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions.

In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

- RELISTOR tablets (≥ 2% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).
- RELISTOR injection (≥ 1% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

- RELISTOR injection (≥ 5% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%) flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

Please see complete Prescribing Information for RELISTOR at [www.bauschhealth.com](http://www.bauschhealth.com). For more information about RELISTOR, please visit [www.RELISTOR.com](http://www.RELISTOR.com).

**About PROGENICS**

Progenics is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer, including: therapeutic agents designed to treat cancer (AZEDRA®, 1095, and PSMA TTC); prostate-specific membrane antigen ("PSMA") targeted imaging agents for prostate cancer (PyL™ and 1404); and imaging analysis technology (aBSI and PSMA AI). Progenics

has two commercial products, AZEDRA, for the treatment of patients with unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (rare neuroendocrine tumors of neural crest origin) who require systemic anticancer therapy; and RELISTOR® (methylnaltrexone bromide) for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies Inc.

### **Forward Looking Statements**

*This press release contains projections and other “forward-looking statements” regarding future events. Statements contained in this communication that refer to Progenics’ estimated or anticipated future results or other non-historical facts are forward-looking statements that reflect Progenics’ current perspective of existing trends and information as of the date of this communication and include statements regarding Progenics’ strategic and operational plans and delivering value for shareholders. Forward looking statements generally will be accompanied by words such as “anticipate,” “believe,” “plan,” “could,” “should,” “estimate,” “expect,” “forecast,” “outlook,” “guidance,” “intend,” “may,” “might,” “will,” “possible,” “potential,” “predict,” “project,” or other similar words, phrases or expressions. Such statements are predictions only, and are subject to risks and uncertainties that could cause actual events or results to differ materially. These risks and uncertainties include, among others: market acceptance for approved products; the risk that the commercial launch of AZEDRA may not meet revenue and income expectations; the cost, timing and unpredictability of results of clinical trials and other development activities and collaborations; the unpredictability of the duration and results of regulatory review of New Drug Applications (NDA) and Investigational NDAs; the inherent uncertainty of outcomes in the intellectual property disputes such as the dispute with the University of Heidelberg regarding PSMA-617; our ability to successfully develop and commercialize products that incorporate licensed intellectual property; the effectiveness of the efforts of our partners to market and sell products on which we collaborate and the royalty revenue generated thereby; generic and other competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; possible product safety or efficacy concerns, general business, financial, regulatory and accounting matters, litigation and other risks ; the costs and management distraction attendant to activist shareholder campaigns; and risks related to changes in the composition of our Board of Directors following our 2019 Annual Meeting of Shareholders. More information concerning Progenics and such risks and uncertainties is available on its website, and in its press releases and reports it files with the Securities and Exchange Commission (the “SEC”), including those risk factors included in its Annual Report on Form 10-K for the year ended December 31, 2018, as updated in its subsequent Quarterly Reports on Form 10-Q. Progenics is providing the information in this press release as of its date and, except as expressly required by law, Progenics disclaims any intent or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.*

*Additional information concerning Progenics and its business may be available in press releases or other public announcements and public filings made after this press release. For more information, please visit [www.progenics.com](http://www.progenics.com). Information on or accessed through our website or social media sites is not included in the company’s SEC filings.*

(PGNX-F)

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