Progenics Pharmaceuticals Announces Third Quarter 2018 Financial Results And Business Update

November 8, 2018

- AZEDRA® (iobenguane I 131) Approved by U.S. Food and Drug Administration (FDA)
- AZEDRA U.S. Launch Progressing and AZEDRA Added to the NCCN Guidelines and Four CMS-Recognized Drug Compendia
- Phase 3 Study of PyL™ for the Detection of Biochemical Recurrence of Prostate Cancer to Begin by Year End
- Company Advancing 1095, PSMA-Targeted Therapeutic for Metastatic Prostate Cancer, into Phase 2 Development
- Third Quarter 2018 RELISTOR® Net Sales Total $34.5 Million

NEW YORK, Nov. 08, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced financial results and provided a business update for the third quarter of 2018.

"The third quarter was marked by multiple successes on the clinical and regulatory front, including the approval and launch of AZEDRA, the first-ever U.S. approved treatment for advanced or metastatic pheochromocytoma and paraganglioma. The broader medical community has recognized the importance of AZEDRA in treating these deadly tumors, and we are pleased with the high level of interest from across the entire spectrum of the healthcare system and well as the rapid addition of AZEDRA to the NCCN guidelines," commented Mark Baker, Chief Executive Officer of Progenics.

Mr. Baker continued, "We are pleased that clinicians and pharmaceutical industry leaders increasingly recognize the value of radiopharmaceuticals to address a range of unmet needs in oncology. Consistent with our strategy to maximize the full value of our PSMA-targeted radio pharmaceutical candidates, we are advancing our prostate cancer pipeline. Following encouraging data from our PyL Phase 2/3 OSPREY study, we are on track to initiate a Phase 3 study this year. In addition, we are moving forward a Phase 2 study for 1095 in patients with metastatic castration-resistant prostate cancer (mCRPC) in early 2019."

Third Quarter and Recent Key Business Highlights

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

- **AZEDRA Launch Progressing Following FDA Approval in July**
  In July, Progenics received U.S. Food and Drug Administration (FDA) approval of its New Drug Application for AZEDRA. 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.

- **AZEDRA Added to NCCN Guidelines and Four CMS-Recognized Drug Compendia**
  In September 2018, AZEDRA was added to the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology for Neuroendocrine and Adrenal Tumors v 3.2018. NCCN Guidelines® are widely recognized and used as the standard for clinical policy in oncology by clinicians and payors. Since AZEDRA's approval by the FDA, it has also been added to four drug compendia: Clinical Pharmacology©; DRUGDEX®; Lexi-Drugs®; and NCCN. These compendia are recognized by private and public payers, including Centers for Medicare and Medicaid Services (CMS) as authoritative sources to be considered in determining drug reimbursement.

- **Pivotal trial of AZEDRA published in *The Journal of Nuclear Medicine***
  In October 2018, the study entitled, "Efficacy and Safety of High-Specific-Activity I-131 MIBG Therapy in Patients with Advanced Pheochromocytoma or Paraganglioma," was published in *The Journal of Nuclear Medicine*. This article reported the complete results of the pivotal study of AZEDRA, which was the largest multicenter, prospective trial to evaluate the safety and efficacy of any therapy in patients with pheochromocytoma and paraganglioma and formed the basis of AZEDRA's approval by the FDA.

- **AZEDRA Safety and Tolerability Data to be presented at a Special Interest Session at RSNA**
  In November, Progenics will present updated safety and tolerability data for High-Specific-Activity MIBG (AZEDRA®) at the Special Interest Session: High Impact Clinical Trials the 104th Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA).

PSMA-Targeted Prostate Cancer Pipeline

- **Advancing 1095 Therapeutic into Phase 2 Development**
  In October 2018, following discussions with the FDA, Progenics announced plans for a Phase 2 study of 1095 in combination with enzalutamide in chemo-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. It is believed that once 1095 binds to the prostate cancer cells, the drug is internalized and the beta radiation kills the tumor cells. Enrollment is expected to begin in early 2019 and PyL, Progenics' PET/CT imaging agent, will be used to select patients most likely to benefit from 1095 treatment.

- **Company decides to focus PSMA-Targeted Imaging Agent Efforts on PyL, Not Investing in Additional 1404 Trials**
  After review of the results of its Phase 3 study of 1404, a PSMA-targeted small molecule SPECT/CT imaging agent to visualize cancer; and an assessment of the PSMA-targeted imaging agent commercial landscape, the Company has decided to focus its efforts on PyL, its PSMA-targeted PET/CT imaging agent, and will not further invest in 1404.

- **Phase 3 Study of PyL Imaging Agent to Begin by Year End**
  In September 2018, the Company announced topline results of its Phase 2/3 OSPREY study evaluating the diagnostic accuracy of its PSMA-targeted PET/CT imaging agent, PyL, in prostate cancer. The study data highlights the strong positive predictive values of PyL to detect prostate cancer in pelvic lymph nodes and metastatic lesions and supports continued development of PyL. Progenics expects to initiate a Phase 3 study of PyL for the detection of biochemical recurrence of prostate cancer by the end of 2018.

- **Initiation of Phase 1 Study for PSMA-TTC by Bayer Expected in 2018**
  Progenics expects its partner Bayer to initiate a Phase 1 study of PSMA-Targeted Thorium Conjugate (PSMA-TTC) in patients with mCRPC by year end 2018. Bayer was previously granted exclusive worldwide rights to develop and commercialize products using Progenics' PSMA antibody technology in combination with Bayer's alpha-emitting radionuclides.

Digital Technology Portfolio

- **Artificial Intelligence Imaging Analysis Technology to Use 1404 and PyL Data**
  Progenics' imaging analysis technology uses artificial intelligence and machine learning to quantify and automate the reading of PSMA targeted imaging. Data from the company's pipeline of PSMA-targeted imaging agents (1404 and PyL) is being used to develop deep learning algorithms delivered through compliant medical device software for the automatic detection and quantification of prostate cancer images. The use of AI applications can boost performance, increases objectivity and repeatability, and makes complex but clinically relevant assessments available to physicians in the interpretation of large and complex image data.

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

- **Third Quarter 2018 RELISTOR Net Sales of $34.5 Million**
  The third quarter 2018 net sales of RELISTOR, as reported to Progenics by its partner Bausch Health Companies, Inc. (formerly known as Valeant Pharmaceuticals, Inc.), translated to $5.2 million in royalty revenue for Progenics for the quarter.

Third Quarter 2018 Financial Results

Third quarter revenue totaled $5.3 million, up from $2.7 million in the third quarter of 2017, reflecting RELISTOR royalty income of $5.2 million compared to $2.6 million in the corresponding period of 2017.

Third quarter research and development expenses decreased by $2.3 million compared to the corresponding prior year period, resulting primarily from lower external costs associated with the completion of the Phase 2 study for AZEDRA and the Phase 3 trial for 1404. Third quarter selling, general and administrative expenses increased by $1.1 million compared to the corresponding prior year period, primarily attributable to higher costs associated with the commercial launch of AZEDRA. Progenics also recorded a net non-cash charge of $15.2 million in the third quarter 2018, resulting from changes in estimated fair values of intangible assets and contingent consideration liability, primarily related to 1404. For the three months ended September 30, 2018, Progenics recognized interest expense of $1.2 million related to the RELISTOR royalty-backed loan and $1.5 million income tax benefit associated with the non-cash charge recorded as a result of the change in estimated fair value of 1404 intangible assets mentioned above.

Net loss for the third quarter was $24.4 million, or $0.30 per diluted share, compared to net loss of $15.4 million, or $0.22 per diluted share, in the corresponding 2017 period.

Progenics ended the third quarter with cash and cash equivalents of $148.9 million, an increase of $58.2 million compared to cash and cash equivalents as of December 31, 2017. During the quarter, the Company raised net proceeds of $70.0 million in an underwritten public offering of 9.1 million shares of common stock at a public offering price of $8.25 per share and an additional $4.8 million in at-the-market ("ATM") transactions of 0.6 million shares of common stock at an average selling price of $8.36 per share. Progenics intends to use the proceeds to support the launch of AZEDRA, to advance its pipeline and for potential business development opportunities.

Conference Call and Webcast

Progenics will review third quarter financial results in a conference call today at 8:30 a.m. ET. To participate, please dial (877) 250-8889 (domestic) or (720) 545-0001 (international) and reference conference ID 6409609. A live webcast will be available in the Media Center of the Progenics website, www.progenics.com, and a replay will be available 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 September 30,		For the Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenues:	(Unaudited)			
Royalty income	$ 5,169	$ 2,562	$ 11,757	$ 7,282
Other revenues	148	135	627	527
Total revenues	5,317	2,697	12,384	7,809
Operating expenses:				
Research and development	8,090	10,344	25,547	31,641
Selling, general and administrative	7,075	5,958	21,341	17,986
Intangible impairment charge	23,200	-	23,200	-
Change in contingent consideration liability	(8,000)	700	(5,900)	3,300
Total operating expenses	30,365	17,002	64,188	52,927
Operating loss	(25,048)	(14,305)	(51,804)	(45,118)
Other (expense) income:				
Interest (expense) income, net	(762)	(1,047)	(2,698)	(3,230)
Total other (expense) income	(762)	(1,047)	(2,698)	(3,230)
Loss before income tax benefit	(25,810)	(15,352)	(54,502)	(48,348)
Income tax benefit	1,453	-	1,549	-
Net loss	**$ (24,357)**	**$ (15,352)**	**$ (52,953)**	**$ (48,348)**
Net loss per share - basic and diluted	**$ (0.30)**	**$ (0.22)**	**$ (0.70)**	**$ (0.69)**
Weighted average shares outstanding – basic and diluted	**80,325**	**70,270**	**75,648**	**70,233**

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2018	**December 31, 2017**
	(unaudited)	(audited)
Cash and cash equivalents	$ 148,851	$ 90,642
Accounts receivable, net	5,821	3,972
Property and equipment, net	3,977	4,122
Intangible assets, net and goodwill	19,967	43,443
Other assets	3,766	3,778
Total assets	**$ 182,382**	**$ 145,957**
Current liabilities	$ 16,495	$ 15,359
Contingent consideration liability	10,900	16,800
Long-term debt, deferred tax and other liabilities	40,104	50,345
Total liabilities	67,499	82,504
Total stockholders' equity	114,883	63,453
Total liabilities and stockholders' equity	**$ 182,382**	**$ 145,957**

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 ≥160 mmHg with an increase of 20 mmHg or an increase in diastolic blood pressure to ≥ 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 (≥ 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.

Reference:

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

Reference:

AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 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:

<u>OIC in adult patients with chronic non-cancer pain</u>

- 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%).

<u>OIC in adult patients with advanced illness</u>

- 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. For more information about RELISTOR, please visit www.RELISTOR.com.

About PROGENICS

Progenics develops innovative medicines and other technologies to target and treat cancer, including: 1) therapeutic agents designed to treat cancer (AZEDRA®, PSMA TTC and 1095), 2) PSMA-targeted imaging agents for prostate cancer (1404 and PyL™), and 3) imaging analysis technology

(PSMA AI and aBSI). Progenics has two commercial products, AZEDRA, for the treatment of 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 opioid-induced constipation, which is partnered with Bausch Health Companies, Inc.

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. 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; possible product safety or efficacy concerns, general business, financial, regulatory and accounting matters, litigation and other risks. 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 U.S. Securities and Exchange Commission, including those risk factors included in its Annual Report on Form 10-K for the annual period ended December 31, 2017, 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 release. For more information, please visit www.progenics.com. Information on or accessed through our website or social media sites is not included in the company's SEC filings.

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