Following Azedra's Approval, Progenics Pharmaceuticals Announces Second Quarter 2018 Financial Results and Business Update

July 31, 2018

- AZEDRA® (iobenguane I 131) Approved by U.S. Food and Drug Administration (FDA); U.S. Promotion Commences
- Top-Line Data from Phase 3 Trial for PSMA-Targeted SPECT/CT Imaging Agent 1404 Expected in Q3'18
- Top-Line Data from Phase 2/3 Trial for PSMA-Targeted PET/CT Imaging Agent PyL ™ Expected in Q4'18
- Second Quarter 2018 RELISTOR® Net Sales Total $23.5 Million

NEW YORK, July 31, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced financial results and provided a business update for the second quarter of 2018.

"We're extremely proud of our recent accomplishments, most notably the FDA approval of AZEDRA, which is a critical breakthrough for patients suffering from pheochromocytoma or paraganglioma, and completes our transition to a commercial organization focused on oncology," commented Mark Baker, Chief Executive Officer of Progenics. "As we commence the commercial launch of AZEDRA, we continue to advance our portfolio of PSMA-targeted radiopharmaceuticals and artificial intelligence imaging analysis technologies. We expect top-line results from the Phase 3 trial evaluating 1404, our PSMA-targeted SPECT/CT imaging agent, and the Phase 2/3 trial for PyL, our PSMA-targeted PET/CT imaging agent, in the third and fourth quarter of this year, respectively."

Second Quarter and Recent Key Business Highlights

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

- **FDA Approval of AZEDRA for the Treatment of Unresectable, Locally Advanced or Metastatic Pheochromocytoma or Paraganglioma**
  In July 2018, Progenics announced the FDA approval of its New Drug Application (NDA) for AZEDRA. The FDA approval of AZEDRA marks 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.

- **Data from Pivotal Phase 2 AZEDRA Study Presented at ASCO**
  In June 2018, during the American Society of Clinical Oncology (ASCO) Annual Meeting, Progenics presented updated overall survival and safety data from its pivotal Phase 2 study of AZEDRA. Data presented showed the median overall survival time as of December 4, 2017 was 44 months among patients who received two therapeutic doses, compared to 18 months among patients who received only one therapeutic dose. Long-term patient follow-up continues.

PSMA-Targeted Prostate Cancer Pipeline

- **Data from Phase 3 Study of 1404 Expected in Third Quarter**
  In January 2018, Progenics announced the completion of enrollment of its Phase 3 study of 1404, a PSMA-targeted small molecule SPECT/CT imaging agent. The ProSPECT-AS study dosed 471 patients with newly-diagnosed or low-grade prostate cancer, whose biopsy indicates a histopathologic Gleason grade of ≤ 3+4 severity and/or are candidates for active surveillance. The Company expects to announce top-line data in the third quarter of 2018.

- **Enrollment Completed in Phase 2/3 Study of PyL, with Data Expected in Fourth Quarter**
  In June 2018, Progenics announced the completion of enrollment in its Phase 2/3 OSPREY study evaluating the diagnostic accuracy of its PSMA-targeted PET/CT imaging agent, PyL (18F-DCFPyL), in prostate cancer. The OSPREY study enrolled 266 patients with localized high risk prostate cancer and 117 patients with recurrent or metastatic prostate cancer in the U.S. and Canada for a total of 383 patients. The Company expects to announce top-line data in the fourth quarter of 2018.

- **Phase 1 Study of 1095**
  1095, a small molecule radiotherapeutic that selectively binds to PSMA, is in a Phase 1 open-label dose escalation study in patients with metastatic castration-resistant prostate cancer (mCRPC) who have demonstrated tumor avidity to 1095.

- **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

- **Data Validating Artificial Intelligence Imaging Analysis Presented at SNMMI**
  At the 2018 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in June 2018, Progenics presented data demonstrating the utility of its imaging analysis technology, which uses artificial intelligence and machine learning to quantify and automate the reading of PSMA targeted imaging. Data from the Company's Phase 2 study of 1404 was used to develop a deep learning algorithm for the purpose of the automatic detection and quantification of 1404 uptake from SPECT/CT images as compared to a manual process.

- **Imaging Analysis Platform Highlighted in *JAMA Oncology***
  In May 2018, Progenics announced the publication of results from a trial evaluating the use of its automated bone scan index (aBSI) in men with mCRPC in *JAMA Oncology.* aBSI automatically calculates the Bone Scan Index utilizing artificial intelligence to help quantify prostate cancer disease burden. The study demonstrated that aBSI was associated with overall survival and prostate cancer-specific survival ($p<0.001$), time to symptomatic progression ($p<0.001$), and time to opiate use for cancer pain ($p<0.001$).

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

- **Second Quarter 2018 RELISTOR Net Sales of $23.5 Million**
  The second 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 $3.5 million in royalty revenue for Progenics for the quarter. Total second quarter 2018 RELISTOR U.S. net sales increased 44% over the second quarter of 2017.

Second Quarter 2018 Financial Results

Second quarter revenue totaled $3.9 million, up from $2.8 million in the second quarter of 2017, reflecting RELISTOR royalty income of $3.5 million compared to $2.6 million in the corresponding period of 2017.

Second quarter research and development expenses decreased by $1.9 million compared to the corresponding prior year period, resulting primarily from lower clinical trial expenses for AZEDRA and 1404. Second quarter general and administrative expenses increased by $1.2 million compared to the corresponding prior year period, primarily attributable to higher costs associated with building commercial capabilities in preparation for the planned launch of AZEDRA. Progenics also recorded non-cash adjustments of $1.3 million in the second quarter 2018, related to changes in the fair value estimate of the contingent consideration liability. For the three months ended June 30, 2018, Progenics recognized interest expense of $1.2 million related to the RELISTOR royalty-backed loan.

Net loss for the second quarter was $15.2 million, or $0.20 per diluted share, compared to net loss of $16.6 million, or $0.24 per diluted share, in the corresponding 2017 period.

Progenics ended the second quarter with cash and cash equivalents of $87.5 million, a decrease of $3.1 million compared to cash and cash equivalents as of December 31, 2017. In order to continue to maintain a strong financial position, the Company raised $19.4 million in net proceeds from sales of its common stock under its "at-the-market" (ATM) facility in April through July 20, 2018, with $4.8 million received in July.

- Financial Tables follow -

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:	(Unaudited)			
Royalty income	$ 3,530	$ 2,601	$ 6,588	$ 4,720
License revenue	333	147	463	362
Other revenues	15	17	16	30
Total revenues	3,878	2,765	7,067	5,112
Operating expenses:				
Research and development	9,347	11,292	17,457	21,297
General and administrative	7,569	6,333	14,266	12,028
Change in contingent consideration liability	1,300	700	2,100	2,600
Total operating expenses	18,216	18,325	33,823	35,925
Operating loss	(14,338)	(15,560)	(26,756)	(30,813)

Other (expense) income:				
Interest (expense) income, net	(930)	(1,076)	(1,936)	(2,183)
Total other (expense) income	(930)	(1,076)	(1,936)	(2,183)
Loss before income tax benefit	(15,268)	(16,636)	(28,692)	(32,996)
Income tax benefit	96	-	96	-
Net loss	**$ (15,172)**	**$ (16,636)**	**$ (28,596)**	**$ (32,996)**
Net loss per share - basic and diluted	**$ (0.20)**	**$ (0.24)**	**$ (0.39)**	**$ (0.47)**
Weighted average shares outstanding – basic and diluted	**74,017**	**70,202**	**73,271**	**70,214**

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2018	December 31, 2017
	(unaudited)	(audited)
Cash and cash equivalents	$ 87,490	$ 90,642
Accounts receivable, net	3,843	3,972
Property and equipment, net	4,139	4,122
Intangible assets, net and goodwill	43,337	43,443
Other assets	3,702	3,778
Total assets	**$ 142,511**	**$ 145,957**
Current liabilities	$ 14,751	$ 15,359
Contingent consideration liability	18,900	16,800
Long-term debt, deferred tax and other liabilities	46,031	50,345
Total liabilities	79,682	82,504
Total stockholders' equity	62,829	63,453
Total liabilities and stockholders' equity	**$ 142,511**	**$ 145,957**

Approved Use:

AZEDRA® (iobenguane I 131) is a prescription medicine used to treat adult and pediatric patients 12 years and older with cancers known as pheochromocytoma and paraganglioma that are positive for the norepinephrine transporter (as determined by an iobenguane scan), and who require systemic anticancer therapy.

Important Safety Information

AZEDRA can cause serious side effects. If you experience these side effects, your health care provider may need to adjust or stop your treatment. You should always follow your health care provider's instructions. Serious side effects may include:
Radiation exposure: Treatment with AZEDRA will expose you to radiation which can contribute to your overall long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer. Radiation risk is greater in children than in adults. You should stay well hydrated before, during, and after your treatment and urinate frequently. Your doctor will advise you on how to lessen exposure to people who may come into contact with you after AZEDRA treatment.
Bone marrow problems and other cancers: Treatment with AZEDRA may cause your blood cell counts to drop (myelosuppression). You may experience blood-related side effects such as low numbers of cells that are responsible for blood clotting (thrombocytopenia), low numbers of a type of white blood cells (neutropenia), and low red blood cells (anemia). 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 (neutropenia with fever). People with low blood counts can develop serious infections. Your health care provider will routinely check your blood counts and tell you if they are too low. Tell your doctor if you experience any symptoms of low blood counts or infection, such as fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly. Other conditions that you may develop as a direct result of treatment with AZEDRA are blood and bone marrow cancers known as secondary myelodysplastic syndrome (MDS) and leukemia. MDS or 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 other types of cancer.
Thyroid problems: Treatment with AZEDRA may increase your long-term risk of developing an underactive thyroid (hypothyroidism) or thyroid cancer. Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Take all thyroid-blocking agents as prescribed by your doctor to reduce the risk of these problems. You may need life-long monitoring for signs and symptoms of hypothyroidism.
Elevations in blood pressure: During or 24 hours following AZEDRA treatment, you may experience increases of blood pressure (hypertension) as a

result of hormones released from your cancer. Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension. All changes in blood pressure occurred within the first 24 hours after treatment. No life-threatening hypertensive crises have been observed. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA. Tell your doctor if you experience any cardiac-related symptoms.
Kidney problems: Treatment with AZEDRA will expose your kidneys to radiation and may impair their ability to work as normal. In some cases, patients have experienced kidney failure after treatment with AZEDRA. Of the 88 patients who received a therapeutic dose of AZEDRA, 9% developed kidney failure or acute kidney injury, and 22% experienced a decrease in kidney function measured at 6 or 12 months. Your health care provider will monitor your kidneys after treatment using blood tests, particularly if you already have kidney impairment before treatment.
Respiratory problems: Treatment with AZEDRA may cause noninfectious lung inflammation (pneumonitis). Tell your doctor if you experience shortness of breath, difficulty breathing, or cough.
Pregnancy warning: Before treatment with AZEDRA, tell your doctor if you are pregnant or plan to become pregnant. Exposure to radiation from treatment with AZEDRA can harm your unborn baby. Use an effective method of birth control during treatment with AZEDRA and for 7 months (for females) and 4 months (for males) after your final dose. Do not breastfeed during treatment with AZEDRA and for 80 days after your final dose.
Fertility problems: Treatment with AZEDRA may cause infertility due to radiation absorbed by your testes or ovaries over the treatment period that is within the range of exposure where temporary or permanent infertility may be expected.

The most common and most serious side effects of AZEDRA include decreased blood cell counts, nausea, vomiting and fatigue. These are not all the possible side effects of AZEDRA. For more information, ask your health care provider.

Drugs that reduce catecholamine uptake or that deplete catecholamine stores may interact with AZEDRA and may affect how well it works. These drugs were not permitted in the clinical trials. Tell your doctor before starting any medication, including over the counter medications, herbal or dietary supplements.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for AZEDRA.

Distributed by: Progenics Pharmaceuticals, Inc., NY 10007

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:

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. 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. Progenics has two commercial products, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, which is partnered with Bausch Health Companies, Inc.; and 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.

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 planned 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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