Progenics Pharmaceuticals Announces Business Update And Third Quarter 2019 Financial Results

November 7, 2019

- Lantheus Holdings, Inc. to Acquire Progenics to Form an Innovative Commercial Life Sciences Company with a Diversified Portfolio of Precision Diagnostics and Radiopharmaceutical Therapeutics
- AZEDRA Commercial Dosing Progresses in U.S. as New Technology Add-On Payment Became Effective October 1st; Ex-U.S. Managed Access Program for Patients Has Been Initiated
- Discussions with FDA Continue Regarding Life Cycle Management Trial to Support the Expanded Label for AZEDRA
- Topline Data from the Phase 3 CONDOR Trial of PyL™ (^{18}F-DCFPyL) Expected by Year End
- Third Quarter 2019 Revenue of $5.6 Million, including $0.6 Million of AZEDRA sales
- Progenics will not hold Q3 2019 earnings conference call due to pending transaction with Lantheus

NEW YORK, Nov. 07, 2019 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) is providing a business update and has today announced financial results for the third quarter 2019.

"We recently entered into a compelling transaction to combine Progenics with Lantheus. We believe this transaction will accelerate the sales of AZEDRA, optimize our clinical pipeline, generate significant cost synergies, and avoid infrastructure build to create significant long-term shareholder value," stated Mark Baker, CEO. "By leveraging Lantheus' experienced management team, long-standing industry relationships, proven expertise in radiopharmaceutical manufacturing and commercialization, complementary portfolio of innovative products, existing infrastructure and robust resources, we believe we will realize significant value for our shareholders. This strategic transaction offers Progenics shareholders a 35% ownership stake in the combined company with strong prospects for top line growth without requiring additional financial leverage or equity dilution. We remain focused on continuing to advance our commercial efforts for AZEDRA and supporting the continued development of our portfolio of PSMA-targeted radiopharmaceuticals, including PyL and 1095. This is a pivotal time for Progenics, and the Board and management team will continue to take the steps necessary to ensure the Company is best positioned to drive long-term value for all shareholders."

Third Quarter and Recent Key Business Highlights

Corporate Update

- **Lantheus Holdings, Inc. ("Lantheus") to Acquire Progenics to Form an Innovative Commercial Life Sciences Company with a Diversified Diagnostics and Therapeutics Portfolio**
  In October 2019, we announced the signing of a definitive agreement in which Lantheus will acquire Progenics in an all-stock transaction, offering a significant upside opportunity to the combined shareholders from a diversified, high growth portfolio with the potential for strong, growing profits. The combination of Lantheus and Progenics forms a leader in precision diagnostics and radiopharmaceutical therapeutics. The combined company will have significant product and cost synergies that will diversify and sustain growing revenues and will drive incremental profitability and cash flow. The combined company will be led by Lantheus Chief Executive Officer, Mary Anne Heino. Ms. Heino will be supported by Chief Financial Officer, Robert J. Marshall Jr., and Chief Operations Officer, John Bolla. Following the closing, Bradley Campbell, currently a member of Progenics' Board of Directors, will be added as a member of the Board of Directors of Lantheus Holdings.

  The transaction is expected to close in the first quarter of 2020, subject to approval by Lantheus and Progenics stockholders, regulatory approvals, and customary closing conditions. Additional details can be found here.

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

- **AZEDRA Commercial Dosing Progresses in U.S. as New Technology Add-On Payment Became Effective October 1st; Ex-U.S. Managed Access Program for Patients Has Been Initiated**
  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. Third quarter sales of AZEDRA totaled $0.6 million (first therapeutic doses for three new patients and a second therapeutic dose for one patient who previously received a first dose). Sales of therapeutic doses of AZEDRA doubled over the preceding second quarter, and we expect them to double again in the fourth quarter. As a result, our guidance for 2019 AZEDRA sales is approximately $2.0 million. The AZEDRA Managed Access program for appropriate commercial patients in need of the therapy outside the U.S. was initiated which will provide additional access to AZEDRA.

- **Life Cycle Management Trial to Support Expanded Label**
  We recently received comments and are currently in discussions with the U.S. Food and Drug Administration ("FDA") on

our proposed life cycle management study to evaluate AZEDRA in patients with other neuroendocrine tumors (NETs). The proposed study is on clinical hold until we reach agreement with the FDA. Assuming we can reach agreement with the FDA on an amended study, or possibly studies design, we intend to commence them next year.

- **Expansion of Iodine Manufacturing Capacity Continues to Support Expected Increase in Demand for AZEDRA and 1095**
  We are continuing our plans to expand manufacturing capacity for our iodine-based products and to provide redundancy. We are increasing the capacity of our Somerset, New Jersey manufacturing site by adding a second shift to increase to two batches a week from the current one batch a week schedule. We are also planning to build out the two additional existing manufacturing suites at the site to make them suitable for iodine manufacturing. Currently at Somerset, we are capable of producing one batch per week (two to three therapeutic doses). The second shift will double our capacity commencing in the second quarter of 2020. We expect additional iodine manufacturing capability to become available from contract manufacturing partners starting in the second quarter of 2020.

PSMA-Targeted Prostate Cancer Pipeline

- **Topline Data from Phase 3 Trial of PyL (18F-DCFPyL) Expected by Year End**
  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. Topline PyL data is expected by the end of the year. Based on prior 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. We currently estimate that the NDA for PyL will be submitted to the FDA in July 2020.

- **Patient Dosing in Phase 2 Trial of 1095 Ongoing**
  The Company continues to dose patients in the ongoing 120-patient open-label Phase 2 trial of 1095 in combination with enzalutamide in chemotherapy-naïve patients with metastatic castration-resistant prostate cancer (mCRPC) who are PSMA avid by PyL imaging. 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. Currently patients are being dosed at Canadian sites using 1095 produced by our contract manufacturing organization, CPDC. CPDC has not been allowed to ship drug to the U.S. under an import alert. Following lifting of the import ban by the FDA, Progenics will submit a request to utilize the CPDC drug at U.S. sites. We expect that review of our request will be completed by the end of 2019, and initiation of dosing at U.S. clinical sites is expected to begin in the first quarter of 2020.

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

- **Third Quarter 2019 World-Wide RELISTOR Net Sales of $32.7 Million**
  The third quarter 2019 world-wide net sales of RELISTOR, as reported by its partner Bausch Health Companies, Inc., translated to $4.9 million in royalty revenue for Progenics for the quarter compared to $5.2 million for the third quarter of 2018. 2019 year to date U.S. sales of RELISTOR are $82.8 million compared to $76.2 million for the same period in 2018.

Third Quarter 2019 Financial Results

Third quarter revenue totaled $5.6 million, up from $5.3 million in the third quarter of 2018.

Third quarter research and development expenses increased by $3.3 million compared to the corresponding prior year period, primarily resulting from higher costs associated with the 1095 clinical trial, the transition of the Somerset manufacturing site, and initiatives to increase production capacity and provide redundancy for iodine-based products, AZEDRA and 1095. Third quarter selling, general and administrative expenses increased by $4.4 million compared to the corresponding prior year period, primarily due to increases in legal and advisory fees associated with the acquisition agreement with Lantheus and the contested election at our 2019 annual meeting of shareholders and the ongoing consent solicitation campaign. Progenics also recorded non-cash adjustments of $0.5 million in the third quarter of 2019, related to changes in the fair value estimate of the contingent consideration liability. For the three months ended September 30, 2019, Progenics recognized interest expense of $1.0 million related to the RELISTOR royalty-backed loan.

Net loss for the third quarter was $18.8 million, or $0.22 per diluted share, compared to net loss of $24.4 million, or $0.30 per diluted share, in the corresponding 2018 period.

Progenics ended the third quarter with cash and cash equivalents of $64.5 million, a decrease of $73.2 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 AZEDRA, as well as for the capital expenditures to increase production capacity to satisfy increasing expected demand and provide redundancy for iodine-based products.

– Financial Tables Follow –

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,	
	2019	**2018**	**2019**	**2018**
Revenues:	(unaudited)			
AZEDRA product sales	$ 570	$ -	$ 840	$ -
Royalty income	4,912	5,169	12,666	11,757
License and other revenue	131	148	6,354	627
Total revenues	5,613	5,317	19,860	12,384
Operating expenses:				
Cost of goods sold	1,317	-	1,810	-
Research and development	11,439	8,090	36,911	25,547
Selling, general and administrative	11,473	7,075	35,267	21,341
Intangible impairment charge	-	23,200	-	23,200
Change in contingent consideration liability	(500)	(8,000)	1,316	(5,900)
Total operating expenses	23,729	30,365	75,304	64,188
Operating loss	(18,116)	(25,048)	(55,444)	(51,804)
Other (expense) income:				
Interest (expense) income, net	(726)	(762)	(1,833)	(2,698)
Total other (expense) income	(726)	(762)	(1,833)	(2,698)
Loss before income tax benefit	(18,842)	(25,810)	(57,277)	(54,502)
Income tax benefit	-	1,453	-	1,549
Net loss	**$ (18,842)**	**$ (24,357)**	**$ (57,277)**	**$ (52,953)**
Net loss per share - basic and diluted	**$ (0.22)**	**$ (0.30)**	**$ (0.67)**	**$ (0.70)**
Weighted average shares outstanding – basic and diluted	**86,421**	**80,325**	**85,328**	**75,648**

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	September 30, 2019	**December 31, 2018**
	(unaudited)	(audited)
Cash and cash equivalents	$ 64,493	$ 137,686
Accounts receivable, net	6,174	3,803
Property and equipment, net	9,254	3,944
Intangible assets, net and goodwill	24,946	19,740
Operating right-of-use lease assets	13,681	-
Other assets	11,504	4,324
Total assets	**$ 130,052**	**$ 169,497**
Current liabilities	$ 20,144	$ 23,446
Contingent consideration liability	4,300	3,950
Operating lease liability	15,154	-
Long-term debt, deferred tax and other liabilities	34,517	41,026
Total liabilities	74,115	68,422
Total stockholders' equity	55,937	101,075
Total liabilities and stockholders' equity	**$ 130,052**	**$ 169,497**

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: Severe and prolonged myelosuppression occurred during treatment with AZEDRA. 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, 7% 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.

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 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 three 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 oral and subcutaneous formulations of RELISTOR® (methylnaltrexone bromide) for the treatment of opioid-induced constipation, which are 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: risks associated with the proposed merger transaction with Lantheus Holdings, Inc.; 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 as a result of the current consent solicitation. 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. Information on or accessed through our website or social media sites is not included in the company's SEC filings.

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