- Company is developing AZX1103 for the prevention of nosocomial infections induced by administration of several classes of antibiotics
- AZX1103 shown to be safe and biologically active in a well-established pre-clinical model

BROOKLYN, N.Y., April 18, 2018 (GLOBE NEWSWIRE) -- AzurRx BioPharma Inc. (NASDAQ:AZRX) ("AzurRx" or the "Company"), today announces positive preclinical results for AZX1103, a b-lactamase enzyme combination product being developed for the prevention of hospital-acquired gastro-intestinal infections.

AZ1103 is designed to be a complementary treatment for patients receiving antibiotics in the hospital setting. The results from the preclinical studies showed that AZX1103 had activity and degraded amoxicillin in the presence of clavulanic acid in the upper GI tract in the Gottingen minipig model.

"The data from these studies are very encouraging, showing AZ1103 to be safe and capable of inactivating amoxicillin, a member of the widely used class of b-lactam antibiotics," said Thijs Spoor, CEO of AzurRx. "We are developing AZX1103 to prevent hospital acquired infections, such as those caused by *Clostridium difficile* (C. diff) and vancomycin resistant enterococcus (VRE). The next steps in this program will be to conduct toxicity studies in animals with the goal of receiving the regulatory approvals to enter the clinic."

The series of preclinical studies investigated oral delivery of AZ1103 using three different capsule formulations: immediate-release, enteric-delivery or colonic-delivery. In all three formulations and at all doses tested, AZ1103 appeared to be well tolerated. No side effects were observed and the animals showed normal behavior, standard food consumption and body weight gain. There was no evidence of acute toxicity, and no severe immunoallergic reactions were seen at doses of up to 180mg/day. The favorable safety profile is partly the result of AZ1103 not being absorbed by the gut and entering the bloodstream. This property was confirmed by ELISA testing, which did not detect the enzyme in AZ1103 in the animal sera.

About AZX1103, An Enzymatic Combination for Prevention of Hospital Infections

AZX1103 is a b-lactamase enzyme combination product of bacterial origin for the prevention of hospital-acquired infections (known as nosocomial infections) and antibiotic-associated diarrhea (AAD) caused by resistant bacterial strains induced by parenteral administration of several antibiotic classes, including the b-lactams. AZ1103 is not

absorbed in the gut, meaning that it will not disrupt the activity of antibiotics that are being administered IV to treat severe infections. However, AZ1103 can inactivate b-lactam antibiotics once they reach the large intestine, thus preventing the harmful disruptions to the gut microbiome that lead to diarrhea.

The Centers for Disease Control, (CDC) has estimated that approximately 1.7 million hospital-associated infections (i.e. ~5% of the number of hospitalized patients), cause or contribute to 99,000 deaths each year in the U.S., with the annual cost ranging from $4.5 - $11.0 billion.

About AzurRx BioPharma, Inc.:

AzurRx BioPharma, Inc. (NASDAQ:AZRX) is engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders. MS1819 recombinant lipase for exocrine pancreatic insufficiency is the company's lead development program, and additional early stage research is being conducted for the prevention of hospital-acquired infections. The company is headquartered in Brooklyn, NY, with scientific operations based in Langlade, France. Additional information on the company can be found at www.azurrx.com

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigations Reform Act of 1995. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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