



FOR IMMEDIATE RELEASE

August 19, 2020

Pharmaceuticals International, Inc.

Nithin Stephen

Associate Director, Business Management

Phone: (410) 584-0001

[Email](#) [Linkedin](#)

**Humanetics Corporation and Pharmaceuticals International, Inc.
Announce Partnership in Support of BIO 300 Clinical Trial
in COVID-19 Patients**

PRESS RELEASE Hunt Valley, MD (August 19, 2020) Humanetics Corporation and Pharmaceuticals International, Inc. (Pii) will work together to support a clinical trial of BIO 300 in COVID-19 patients.

The study will focus on patients who were treated for severe COVID-19, discharged from the hospital, and continue to recover at home. These patients face the possible risk that their respiratory complications will continue to progress, leading to long-term impairment similar to the lasting effects of Severe Acute Respiratory Syndrome (SARS).

The study will compare the lung function, exercise capacity and quality of life in COVID-19 survivors who receive BIO 300, against a group receiving a placebo. The primary endpoint of the trial will be at 12 weeks and patients will be followed for one year.

BIO-300 is a unique, highly selective modulator of inflammation, cell cycle arrest and DNA damage repair being developed for several indications including oncology and defense countermeasures. The patented formulation using suspended nanoparticle technology for improved oral bioavailability, was developed by Humanetics initially for the U.S. Department of Defense to protect military members from harm caused by ionizing radiation. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, awarded funding to conduct the study of BIO 300 for treating the long-term impacts of severe COVID-19.

The study will be conducted by physicians at NYU Langone Health with clinical trial material manufactured by Pii, a US-based contract development and manufacturing organization (CDMO). Humanetics and Pii have worked closely together since 2014 on the development of manufacturing techniques for BIO 300 that increase the drug's oral absorption properties. These improved characteristics allow BIO 300 to be taken by COVID-19 patients in the convenience of their homes. Previous clinical supplies of BIO 300 manufactured by Pii have

been used in a clinical trial of non-small lung cancer patients receiving radiation treatments.

There is a growing concern about the long-term health effects caused by COVID-19 infection. Data from survivors show that a significant number have measurable lung damage at discharge from the hospital, which can linger and progress to additional lung abnormalities, including permanent fibrosis. BIO 300 is one of the therapies to be tested in the growing number of survivors who need treatments to mitigate this progressive lung damage.

Founded in 1988, Humanetics is a privately held, clinical stage pharmaceutical company located in the Minneapolis metropolitan area focused on enhancing human health and wellbeing. In 2003, Humanetics entered the field of radiation modulators through a cooperative research program with the Armed Forces Radiobiology Research Institute (AFRRI). AFRRI's mission is the discovery and early development of drugs that can protect service members from the harmful effects of radiation. From this cooperative program, BIO 300 emerged as a lead candidate and the underlying technology was in-licensed from the Department of Defense to Humanetics. There are two open INDs for BIO 300 for its use in biodefense and oncology indications. The COVID-19 Phase 2 clinical trial is expected to begin in the early Fall of 2020. Learn more at <https://www.humaneticscorp.com/>.

Pharmaceuticals International, Inc. (Pii) is a US-based contract development and manufacturing organization (CDMO) with a passion for solving problems efficiently with the highest quality standards. Pii's Hunt Valley, Maryland campus includes 70 manufacturing for both oral and injectable manufacturing. Our professionals have extensive experience with small and large molecule compounds, developing and manufacturing complex oral and parenteral drugs as well as extended-release formulations, suspensions, and other dosage forms. Learn more at <https://www.pharm-int.com/>.

###