PHATHOM PHARMACEUTICALS SUBMITS TWO NDAS TO U.S. FDA FOR VONOPRAZAN-BASED TREATMENT REGIMENS FOR THE TREATMENT OF H. PYLORI INFECTION

FLORHAM PARK, N.J., (GLOBE NEWSWIRE) – Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, announced that it has submitted two new drug applications (NDAs) to the U.S. Food and Drug Administration (FDA) for the use of vonoprazan in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) and vonoprazan in combination with amoxicillin (vonoprazan dual therapy) as a treatment for Helicobacter pylori (H. pylori) infection in adults. With current standard of care therapies, H. pylori eradication rates have declined in the U.S. If approved, vonoprazan-based treatments offer two new therapeutic options that have demonstrated superior eradication rates as compared to standard of care lansoprazole-based triple therapy.

"The submission of these NDAs is the first step towards addressing the declining H. pylori eradication rates in the U.S. and providing new potential treatment options for the millions of H. pylori sufferers in need of more efficacious treatments," said Azmi Nabulsi, M.D., Chief Operating Officer at Phathom. "Today's announcement underscores Phathom's commitment to changing the treatment landscape for acid-related diseases. If approved, patients and healthcare providers would have two novel options to combat this highly prevalent bacterial infection. We look forward to working with the FDA to advance these vonoprazan-based treatment regimens toward approval. If approved, we anticipate launch in the U.S. in the second half of 2022."

These NDAs are based on the positive data previously announced from Phathom's pivotal Phase 3 PHALCON-HP trial, the largest U.S. registrational trial ever conducted for H. pylori. The study evaluated eradication rates of H. pylori infection using vonoprazan triple therapy and vonoprazan dual therapy compared to lansoprazole-based triple therapy. Vonoprazan triple therapy and vonoprazan dual therapy successfully met the study's primary non-inferiority endpoints and all secondary endpoints, demonstrating superior eradication rates versus lansoprazole-based triple therapy among all patients including in patients with clarithromycin resistant strains of H. pylori.

The FDA has previously designated vonoprazan triple therapy and vonoprazan dual therapy as qualified infectious disease products (QIDP) and awarded them Fast Track designation, in each case, for the treatment of H. pylori infection. In connection with the NDA submissions, Phathom requested Priority Review, which, if granted, will shorten the review period from 10 months to 6 months following FDA acceptance of the submissions for filing.

About Helicobacter pylori (H. pylori) infection

H. pylori is a bacterial pathogen that is estimated to infect over 200 million individuals in the United States and Europe. Approximately 50% of the world and 36% of the US population are infected with the bacterium.[1] In many cases, H. pylori is acquired in childhood and through intrafamilial transmission.[2] As a result of the chronic inflammation induced by H. pylori infection, infected patients develop a range of pathologies including dyspepsia, peptic ulcer disease, gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma.[3] Studies have found that roughly 1 in 5 patients treated for H. pylori will fail first line therapy when using standard clarithromycin triple therapy.[2,4]

About PHALCON-HP

PHALCON-HP was a randomized, multicenter, Phase 3 trial that enrolled 1046 patients of which

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992 patients with a confirmed H. pylori infection were randomized to one of three arms: vonoprazan 20 mg administered twice a day (BID) and amoxicillin 1g administered three times a day (TID) (n=324); vonoprazan 20 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID (n=338); and lansoprazole 30 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID (n=330). Each treatment regimen was administered for 14 days. Diagnoses of infection and test of cure were confirmed by 13C-urea breath test. Additional efficacy analyses were conducted using the pre-specified per protocol population (n=822), a subset of the mITT population comprised of patients who were protocol compliant.

About Vonoprazan

Vonoprazan is an investigational, oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (H. pylori) infection. The FDA has awarded qualified infection disease product (QIDP) status and granted Fast Track designation to vonoprazan in combination with both amoxicillin and clarithromycin and with amoxicillin alone for the treatment of H. pylori infection. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 19 Phase 3 trials for vonoprazan and received marketing approval in Japan and numerous other countries in Asia and Latin America.

About Phathom

Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases and disorders. Phathom has in-licensed the exclusive rights in the United States, Europe, and Canada to vonoprazan, a novel potassium competitive acid blocker (P-CAB) in late-stage development for the treatment of acid-related disorders.

For more information about Phathom, visit the Company's website at:

phathompharma.com
or follow the Company on social media:
LinkedIn at:

linkedin.com/company/phathompharma
and Twitter **@PhathomPharma**

Forward Looking Statements

Phathom cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential acceptance and approval by the FDA of our NDAs for vonoprazan; the ability of vonoprazan-based treatments to address declining H. pylori eradication rates; and our plans to commercially launch vonoprazan in the second half of 2022. The inclusion of forward-looking statements should not be regarded as a representation by Phathom that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Phathom's business, including, without limitation: the FDA may disagree that the existing safety and efficacy data is sufficient to accept or approve the NDAs; the inherent risks of clinical development of vonoprazan; Phathom's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of vonoprazan that may limit its development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; Phathom's

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ability to maintain undisrupted business operations due to the COVID-19 coronavirus, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's Annual Report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Phathom undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

1. Hooi et al. Gastroenterology. 2017;153:420.
2. Chey et al. Am J Gastroenterol.2017;112:212.
3. Malfertheiner et al. Gut. 2017;66:6.
4. Alsamman et al. Dig Dis Sci. 2019;64:2893.

FUJIFILM UNVEILS ADVANCED IMAGE ENHANCEMENT TECHNOLOGY UPGRADE FOR ELUXEO ENDOSCOPIC IMAGING SYSTEM AT SAGES 2021

This technology is the first in-market solution to enable visualization of hemoglobin oxygen saturation (StO2) levels in tissue during laparoscopic and endoluminal procedures

Lexington, Mass. – FUJIFILM Medical Systems U.S.A., Inc., a leading provider of endoscopic and endosurgical imaging technology, announces the commercial launch of the ELUXEO® 7000X System, a new video imaging technology developed to enable real-time visualization of hemoglobin oxygen saturation (StO2) levels in tissue using laparoscopic and/or endoluminal imaging.

The ELUXEO 7000X is an upgrade to the company's ELUXEO® Endoscopic Imaging System, and was unveiled at the annual Society

of American Gastrointestinal and Endoscopic Surgeons (SAGES) conference, held August 31 – September 3 at Sands Expo Convention Center in Las Vegas Nevada. The ELUXEO Endoscopic Imaging System revolutionized endoscopic visualization when it was introduced to the U.S. market in 2018 with its proprietary 4-LED Multi-light technology. The ELUXEO 7000X System employs 5-LED technology to enable this enhanced imaging capability.

Enabling the visualization and analysis of StO2 levels helps surgeons more accurately identify potentially ischemic tissue, better positioning surgeons to address and prevent tissue necrosis.

Today's standard for visualizing tissue perfusion is to leverage fluorescent imaging using indocyanine green (ICG) dye - a method in which an injectable dye circulates through the bloodstream and is excited using near-infrared light. Physicians then use that excited dye to identify blood flow. Fujifilm's innovation was developed to address potential limitations resulting from ICG:

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- Intravenous dye injections are not required prior to imaging.
- GI tract observation time frame can be extended as liver filtration of ICG dye is no longer a factor.

In addition, ICG does not allow physicians to detect potential ischemic tissue during endoluminal procedures, making the ELUXEO 7000X the only product on the market to enable this visualization via StO2 measurements.

The technology was granted "breakthrough device" designation by the U.S. Food and Drug Administration (FDA) in September, 2020, and received 510(k) clearance from the FDA on June 30, 2021.

The endosurgical research team at Fujifilm has been working closely on clinical usage of the technology with key opinion leaders from top medical centers in the United States and Japan.

"I find the ELUXEO 7000X System to be a game changing technology in the fields of MIS and endosurgery," says Paul Curcillo, MD, FACS, Department of Surgical Oncology, Division of Minimally Invasive Surgery, Fox Chase Cancer Center. "The ability for real-time assessment of StO2 allows me to identify tissue necrosis without factoring in time restrictions and the need for consumables. In addition, we can use it in any laparoscopic case we are doing with our existing ELUXEO endoscopic imaging system."

"Our ELUXEO product portfolio is engineered to revolutionize conventional minimally-invasive and endoluminal procedures and to raise the standard of patient care," said Taisuke Fujita, vice president, Endoscopy Division, FUJIFILM Medical Systems U.S.A. "Fujifilm continues to draw on our traditional medical imaging and optical expertise to meet today's needs of surgeons across the entire clinical spectrum."

Same suite, single cart

The Fujifilm ELUXEO System allows minimally invasive and endoluminal procedures to be performed in the same suite using a single tower, reducing the amount of valuable space needed in the OR.

"The American Board of Surgery now requires surgeons to be trained in flexible endoscopy, powering the rise in surgeons' use of less invasive endoluminal techniques," added Fujita. "The ELUXEO Endoscopic Imaging System is a surgical device disruptor, empowering enhanced procedural workflow, and optimizing space in surgical suites."

The ELUXEO Endoscopic Imaging System is uniquely engineered with 4-LED Multi-light technology, combining brilliantly clear white light imaging with Linked Color Imaging (LCI®) and Blue Light Imaging (BLI) modes. The result is unparalleled image clarity and visualization in full high definition to enhance observation, improve detection, and enable full characterization. Surgeons using LCI can clearly see and distinguish anatomical structures of tissue, fat, and vessels to more accurately and precisely determine incision placement.

About Fujifilm

FUJIFILM Medical Systems U.S.A., Inc. is a leading provider of unrivaled diagnostic imaging products and medical informatics solutions that meet the evolving needs of healthcare facilities today and into the future. Medical imaging solutions span digital

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radiography (DR), detectors, portables and suites, mammography systems with digital breast tomosynthesis, computed tomography solutions for oncology and radiology applications, as well as technologically advanced flexible and surgical endoscopy solutions. Fujifilm enables interoperability through its Systems Integration offering as well as its comprehensive, AI-supported Synapse® Enterprise Imaging portfolio, which includes the TeraMedica Division of Fujifilm. FUJIFILM Medical Systems U.S.A., Inc. is headquartered in Lexington, Massachusetts. For more information please visit healthcaresolutions-us.fujifilm.com.

FUJIFILM Holdings Corporation, Tokyo, Japan, brings cutting edge solutions to a broad range of global industries by leveraging its depth of knowledge and fundamental technologies developed in its relentless pursuit of innovation. Its proprietary core technologies contribute to the various fields including healthcare, highly functional materials, document solutions and imaging products. These products and services are based on its extensive portfolio of chemical, mechanical, optical, electronic and imaging technologies. For the year ended March 31, 2021, the company had global revenues of $21 billion, at an exchange rate of 106 yen to the dollar. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship.

For more information, please visit:
fujifilmholdings.com

ASPEN MALNUTRITION AWARENESS WEEK: HELPING GI CLINICIANS INTERVENE AND TREAT MALNUTRITION

On October 4-8, 2021, the American Society for Parenteral and Enteral Nutrition (ASPEN) will launch its annual campaign to educate healthcare professionals on detecting, intervening, and treating malnutrition. The 2021 program includes live CME webinars, special interactive Zoom discussions, and a wide array of complimentary videos, podcasts, tools, and resources addressing malnutrition.

The offerings will be of keen interest to gastroenterologists, as malnourished patients have longer hospital stays, higher readmission rates, and increased hospital costs and inpatient death rates.

The American Society for Gastrointestinal Endoscopy and the Society of Gastroenterology Nurses and Associates are among the growing number of more than 110 organizations that support Malnutrition Awareness Week™.

Five of the live webinars, which are free to ASPEN members and supporting organizations, provide continuing medical education credits. They will be offered on the following dates:

- October 4: **Malnutrition Diagnosis and Documentation: Strategies for Success**

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- October 5: **Addressing Malnutrition in COVID-19 Patients: From Hospital to Home**
- October 6: **Collaborating with Non-Nutrition Clinicians on Malnutrition Strategies**
- October 7: **Ramifications of Nutrient Shortages in the Neonatal Population**
- October 8: **Applying Latest Findings from Notable Malnutrition Publications to Your Practice**

Webinar capacity is limited so early registration is strongly recommended.

All other Malnutrition Awareness Week educational materials are available free of charge, including short, on-demand videos that will cover a range of topics including performing nutrition assessment via telehealth in inpatient and outpatient settings.

The videos, podcasts, resources, and other tools, ranging from clinician guides to patient handouts, will be released throughout September and October.

To register for the webinars and to access the complimentary resources, visit:

nutritioncare.org/PG-MAW

About ASPEN

The American Society for Parenteral and Enteral Nutrition (ASPEN) is dedicated to improving patient care by advancing the science and practice of nutrition support therapy and metabolism. It is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With members from around the world, ASPEN is a community of dietitians, nurses, nurse practitioners, pharmacists, physicians, scientists, students, and other health professionals from every facet of nutrition support clinical practice, research, and education.

For more information about ASPEN, please visit:

nutritioncare.org