



Innovate Biopharmaceuticals Acquires Late - Stage Pancreatic Imaging Assets

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- Company Plans to Augment Phase 3 Clinical Data Package to Support Potential Product Approval -

RALEIGH, North Carolina, Jan 5, 2015 (MARKETWIRED) [Innovate Biopharmaceuticals, Inc.](#) (Innovate) has entered into an agreement to purchase all assets related to RG-1068, a synthetic version of human secretin from [Repligen Corporation](#). Repligen has completed a Phase 3 study demonstrating that RG-1068 improved detection of pancreatic duct abnormalities in patients with known or suspected pancreatitis. The acquisition includes a New Drug Application (NDA) filed for RG-1068 with the U.S Food and Drug Administration (FDA), a Marketing Authorization Application (MAA) filed with the European Medicines Agency (EMA), and all related preclinical and clinical data and filings.

Upon completing the pivotal study of RG-1068, and having received orphan drug designation and priority review for the compound, Repligen submitted the NDA and MAA filings for marketing approval of RG-1068 for secretin stimulated Magnetic Resonance Cholangiopancreatography (S-MRCP) in late 2011. The recently published phase III study of S-MRCP vs. MRCP alone vs. Endoscopic Retrograde Cholangiopancreatography (ERCP) elucidates the clinical advantages of using secretin in combination with MRCP (*Gastroenterology* 2014; 147:646-654). In April 2012, the FDA issued a Complete Response Letter to Repligen requiring additional clinical trial data to support a potential product approval. Innovate plans to meet with the FDA and the EMA to discuss the additional study requirements, in preparation to resubmit the NDA and MAA. Under the terms of the purchase agreement, Repligen is eligible to receive royalties from Innovate on any future net sales of RG1068 for all approved indications.

According to Jerry Gardner, M.D., Innovate's Head of Clinical Strategy, "Secretin, the first hormone, was discovered in 1902 based on its ability to stimulate pancreatic fluid and bicarbonate secretion. Its actions in the pancreatic-biliary system have the potential to improve identification by magnetic resonance imaging of structural abnormalities in this system including early cancer. Secretin's actions in the central nervous system may influence food intake and possibly play a role in the treatment of cachexia and obesity."

About Secretin

Secretin is a 27 amino acid long hormone which rapidly stimulates release of pancreatic secretions, thus improving visualization of the pancreatic ducts during imaging procedures. Secretin has also been tested in a variety of central nervous system conditions such as autism, though currently approved only for pancreatic function testing and imaging with ERCP. The currently marketed synthetic secretin, approved in 2004, has been on the FDA Drug Shortage List since 2012 and is not approved by the FDA or the EMA for S-MRCP.

About Secretin - stimulated MRCP

MRCP has been used for more than 20 years as a non-invasive tool for imaging pancreatic ducts. With the addition of secretin, pancreatic secretions are increased leading to significantly improved visualization of the pancreatic ducts for detection of abnormalities, including pancreatic cancer. The gold standard for pancreatic duct imaging had been ERCP, an expensive and invasive procedure with complications such as pancreatitis (3-5%), bleeding (1-2%), perforation (1%), infection (1-2%) and death (1/250). More than a half-million ERCP procedures are performed annually in the US and as the role of ERCP diminishes for screening, it will further the need for approval of secretin for S-MRCP.

About Innovate Biopharmaceuticals, Inc.

Innovate is an emerging biotechnology company focused on developing novel gastroenterology medicines. With the acquisition of RG-1068 (INN-329), Innovate adds a phase III product to its current pipeline. Innovate's other key product, INN-108, is a patent-protected oral small molecule new chemical entity with a novel mechanism of action for mild to moderate Ulcerative Colitis. INN-108 is entering phase II clinical trials in 2015. Innovate owns global rights to both INN-329 and INN-108.

Forward Looking Statements

This press release contains forward-looking statements, including statements regarding the clinical development of our product candidates. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of our product development activities and clinical trials; the approval and commercialization of our product candidates; and risks of increased regulatory requirements; amongst others. These forward-looking statements speak only as of the date hereof. Innovate Biopharmaceuticals disclaims any obligation to update these forward-looking statements.

SOURCE:Innovate Biopharmaceuticals:

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