Horizon Therapeutics' HZT-501 Significantly Reduces Incidence of NSAID-Induced Upper Gastrointestinal Ulcers in Patients with Mild-to-Moderate Pain

Data from Phase 3 REDUCE-1 and REDUCE-2 Studies Demonstrate that Novel Combination Treatment Decreases Risk of Developing GI Ulcers by Approximately 50 Percent --Data presented today at 56th Annual Digestive Disease Week Meeting in Chicago--

CHICAGO, Ill., June 1, 2009 - Horizon Therapeutics, Inc., a privately held biopharmaceutical company, today presented data at the 56th Annual Digestive Disease Week (DDW) meeting from two pivotal Phase 3 trials evaluating its lead compound HZT-501, which demonstrated that patients with mild-to-moderate pain treated with HZT-501 developed 50 percent less NSAID-induced upper gastrointestinal (GI) ulcers (gastric and/or duodenal ulcers) compared to patients treated with ibuprofen alone. HZT-501 is a novel, proprietary fixed-dose combination tablet containing the most prescribed non-steroidal anti-inflammatory drug (NSAID), ibuprofen, and famotidine, the most potent H_2 antagonist.

"NSAIDs, such as ibuprofen, are among the most widely used drugs in the world," said Loren Laine, MD, professor of medicine, University of Southern California. "NSAIDs are effective at treating pain, but they also increase the risk of developing ulcers in the stomach or intestine and the risk of developing ulcer complications, such as bleeding. Patients at increased risk for gastrointestinal ulcers may benefit from protective co- therapy, although many such patients do not receive or adhere to this co-therapy."

The presentation at DDW included data from more than 1,300 evaluable patients who participated in the **R**egistration **E**ndoscopic Study to **D**etermine **U**lcer Formation of HZT-501 **C**ompared to Ibuprofen: **E**fficacy and Safety Study, or REDUCE-1 and REDUCE-2. The primary objective of these studies was to evaluate the proportion of patients treated with HZT-501 (800 mg ibuprofen and 26.6 mg famotidine) or ibuprofen (800 mg) alone who developed endoscopically diagnosed gastric and/or duodenal ulcers during a 24-week treatment period. The results for each study were analyzed using both life-table and crude-rate statistical methods. Results are listed in the table below:

	REDUCE 1 (n=812)			REDUCE 2 (n=570)		
	HZT-501 (n=550)	**Ibuprofen (n=262)**	**P-value**	**HZT-501 (n=380)**	**Ibuprofen (n=190)**	**P-value**
No. of patients developing upper GI ulcers	62	61		40	38	
Life Table Analysis (%)	14.7	29.1	0.0002	13.8	22.6	0.0304
	11.3	23.3	0.0001	10.5	20	0.0018
Crude Rate Analysis (%)						

Treatment with HZT-501 was well-tolerated. The most commonly reported adverse events in these two studies were dyspepsia,

nausea, diarrhea, constipation, headache and upper respiratory tract infection. The majority were mild to moderate in severity. There were no significant differences in adverse event or serious adverse event profiles between the two treatment groups. One death occurred in the ibuprofen group due to an overdose of Tylenol®.

“Patients treated with HZT-501 were approximately half as likely to develop upper GI ulcers compared to patients treated with ibuprofen alone,” said Timothy P. Walbert, president and chief executive officer of Horizon Therapeutics. “These data provide compelling evidence for the promise of HZT-501 in treating patients with mild to moderate pain who are at risk for upper GI ulcers.”

NSAIDs, such as ibuprofen, are among the most widely used drugs in the world for the treatment of chronic pain and inflammation with more than 90 million prescriptions written each year for the treatment of arthritis and other types of mild-to-moderate pain. However, NSAIDs are associated with a range of adverse side effects, which primarily affect the GI tract. Up to 30 percent of patients taking NSAIDs experience GI ulcers, and even more suffer from upper GI symptoms (e.g., dyspepsia, heartburn). Serious NSAID-induced GI toxicity causes an estimated 16,500 deaths and more than 107,000 hospitalizations annually in the U.S. alone.

Famotidine, when used at high doses (80 mg), has shown a significant two-fold reduction in the incidence of NSAID-induced ulcers. In addition, famotidine provides other distinct advantages, including an excellent long term safety profile with more than 20 million patients treated worldwide, demonstrated safety up to 10 times the approved prescription dose at six months and data supporting low risk of serious adverse events. The most frequent adverse effects reported with the use of single ingredient famotidine include headache.

About REDUCE-1 and REDUCE-2
REDUCE-1 and REDUCE-2 were two randomized, double-blind, controlled trials that enrolled more than 1500 patients with mild-to-moderate pain. Patients were randomly assigned, in approximately a 2:1 ratio, to receive either HZT-501 (800 mg ibuprofen and 26.6 mg famotidine) or ibuprofen (800 mg) alone orally three times daily for a 24-week treatment period or until patients developed either an endoscopically diagnosed upper gastrointestinal ulcer and/or prohibitive toxicity. Patients received endoscopies at baseline and weeks 8, 16 and 24.

The primary efficacy objective of REDUCE-1 was to evaluate HZT-501 in reducing the proportion of patients who develop endoscopically diagnosed gastric ulcers during the 24-week treatment period, as compared to ibuprofen, in patients at risk for NSAID-induced ulcers. The primary objective of REDUCE-2 was to evaluate HZT-501 in reducing the proportion of patients who develop endoscopically diagnosed gastric and/or duodenal ulcers during the 24-week treatment period, as compared to ibuprofen, in patients at risk for NSAID-induced ulcers. The trials were conducted via a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA).

About HZT-501
HZT-501 is a novel, proprietary fixed-dose tablet combining the world's most prescribed NSAID, ibuprofen, with a high dose of the most potent H 2 antagonist, famotidine, in a single pill. It is anticipated that HZT-501 will provide effective pain relief and reduce stomach acidity during the peak time of ulceration risk, thus reducing the risk of NSAID-induced ulcers.

About the Arthritis and Pain Market
According to the Arthritis Foundation, arthritis affects 46 million people in the U.S. and costs the U.S. economy $128 billion annually. According to a study by the Centers for Disease Control and Prevention (CDC) for the National Arthritis Data Workgroup, due to the increasing aging population, arthritis is projected to increase by 40 percent in the next two decades. The CDC estimates that 67 million people will be affected by arthritis by 2030. Additionally, chronic pain affects an estimated 86 million American adults. NSAIDs are among the most widely used drugs in the world for the treatment of arthritis and pain and are a major cause of GI complications, including ulcers. NSAIDs block enzymes and reduce prostaglandins throughout the body and as a consequence, ongoing inflammation, pain, and fever are reduced. Because the prostaglandins that protect the stomach are reduced, NSAIDs often cause ulcers in the stomach. NSAID-induced GI toxicity causes an estimated 16,500 deaths and more than 107,000 hospitalizations annually in the U.S. alone.

If deaths from the gastrointestinal effects of NSAIDs were tabulated separately in the National Vital Statistics reports, these effects would equate to the 15th most common cause of death in the U.S. Studies have shown that less than 30 percent of high-risk NSAID patients are co-prescribed a gastro-protective agent in combination with their NSAID. In addition, patient adherence to a regimen of separate pain and GI protective medications has also been shown to be poor.

About Digestive Disease Week (DDW)
DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 31 – June 4, 2009, at McCormick Place Convention Center , Chicago , IL . The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit www.ddw.org .

About Horizon Therapeutics
Horizon Therapeutics, Inc. is a late-stage biopharmaceutical company focused on the development and commercialization of therapies for the treatment of mild-to-moderate pain and arthritis. Horizon's clinical portfolio includes innovative combination therapies in early- and late-stage development that are designed to improve safety, efficacy and patient compliance. For more information about the company and its products, please visit www.horizontherapeutics.com .

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