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HD **InterMune Announces Resubmission Of NDA For Pirfenidone For The Treatment Of Patients With IPF**

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BRISBANE, Calif., May 27, 2014 /PRNewswire/ -- InterMune, Inc. (Nasdaq: ITMN) today announced that it has resubmitted its pirfenidone New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in response to a Complete Response Letter (CRL) received in May 2010. Pirfenidone is being developed for the treatment of adult patients with idiopathic pulmonary fibrosis (IPF).

"We are pleased to have resubmitted the pirfenidone NDA and look forward to our interactions with the FDA," said Dan Welch, Chairman, Chief Executive Officer and President of InterMune. "The final steps in preparing the resubmission were completed very smoothly and efficiently, allowing us to complete the process somewhat earlier than expected. If the FDA grants approval of our NDA within the six-month review period of an NDA resubmission, we would be ready to launch pirfenidone in the first quarter of 2015."

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Under the Prescription Drug User Fee Act (PDUFA), the FDA has 74 days after receipt of an NDA to evaluate the submission in order to determine if it is sufficiently complete. If in this 74-day period the FDA determines that the submission is complete, the review clock will be deemed to have started as of the date that the resubmission was initially received by the FDA. As the resubmission of an efficacy supplement, the submission of the ASCEND data represents a Class 2 resubmission that has a target FDA review of six months under PDUFA V.

In May 2010, InterMune received a CRL from the FDA. In the CRL, the FDA recommended an additional Phase 3 clinical trial to support the efficacy of pirfenidone. Since the receipt of the CRL, InterMune has conducted the Phase 3 ASCEND trial of pirfenidone in IPF, and results of that trial were presented on May 18, 2014, at the meeting of the American Thoracic Society and were published on-line the same day in the New England Journal of Medicine. The NDA resubmission includes the ASCEND Clinical Study Report as well as the pooled analyses of efficacy and mortality from the three InterMune Phase 3 trials: ASCEND and the previous Phase 3 CAPACITY trials (004 and 006). Additionally, the NDA resubmission includes a safety update of approximately 15,000 patients including clinical studies and the extensive post-marketing experience of pirfenidone collected since 2008.

About ASCEND

ASCEND (Assessment of Pirfenidone to Confirm Efficacy and Safety in IPF) is a multinational, randomized, double-blind, placebo-controlled Phase 3 trial designed to evaluate the safety and efficacy of pirfenidone in patients with IPF. Patients (N=555) were randomly assigned 1:1 to receive oral pirfenidone (2403 mg/day) or placebo and were enrolled at 127 centers in the United States, Australia, Brazil, Croatia, Israel, Mexico, New Zealand, Peru and Singapore.

About CAPACITY

The CAPACITY program consisted of two concurrent 72-week trials (studies 004 and 006) which enrolled a total of 779 patients. Both trials were multinational, randomized, double-blind, and placebo-controlled. The studies were designed to evaluate the safety and efficacy of pirfenidone in IPF patients with mild to moderate impairment in lung function. The primary endpoint in both studies was the change from Baseline to Week 72 in percent predicted FVC. This endpoint was met with statistical significance in study 004 (p=0.001). The primary endpoint was not met in study 006 (p=0.501).

About Pirfenidone

Pirfenidone is an orally active, anti-fibrotic agent that inhibits the synthesis of TGF-beta, a chemical mediator that controls many cell functions including proliferation and differentiation, and plays a key role in fibrosis. Pirfenidone also inhibits the synthesis of TNF-alpha, a cytokine that is known to have an active role in inflammation.

On February 28, 2011, the European Commission (EC) granted marketing authorization for Esbriet(R) (pirfenidone) for the treatment of adults with mild to moderate IPF. The approval authorized marketing of Esbriet in all 28 EU member states. Esbriet has since been approved for marketing in Norway and Iceland. In 2011, InterMune launched **commercial** sales of pirfenidone in Germany under the trade name Esbriet, and Esbriet is now also commercially available in various European countries, including key markets such as France, Italy and the UK.

On October 1, 2012, Health Canada approved Esbriet for the treatment of mild to moderate IPF in adult patients. Health Canada designated Esbriet for Priority Review and completed the accelerated review according to target guidelines of 180 days. InterMune launched Esbriet in Canada in January 2013.

Pirfenidone has been marketed as Pirespa(R) since 2008 in Japan and since 2012 in South Korea by Shionogi & Co. Ltd. Under different trade names, pirfenidone is also approved for the treatment of IPF in **China**, India, Argentina and Mexico.

Pirfenidone is not approved for **sale** in the United States.

About IPF

Idiopathic pulmonary fibrosis (IPF) is an irreversible and ultimately fatal disease characterized by progressive loss of lung function due to fibrosis (scarring) in the lungs, which hinders the ability of lungs to absorb oxygen. IPF inevitably causes shortness of breath, and a deterioration in lung function and exercise tolerance. IPF patients follow different and unpredictable clinical courses and it is not possible to predict if a patient will progress slowly or rapidly, or when the rate of decline may change. Periods of transient clinical stability in IPF, when they occur, inevitably give way to continued disease progression. The median survival time from diagnosis is two to five years, with a five-year survival rate of approximately 20-40 percent, which makes IPF more rapidly lethal than many malignancies, including breast, ovarian and colorectal cancers. IPF typically occurs in patients over the age of 45, and tends to affect slightly more men than women.

About InterMune

InterMune is a biotechnology **company** focused on the research, development and commercialization of innovative therapies in pulmonology and orphan fibrotic diseases. In pulmonology, the **company** is focused on therapies for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive, irreversible, unpredictable and ultimately fatal lung disease. Pirfenidone is approved for marketing by InterMune in the EU and Canada under the trade name Esbriet(R). Pirfenidone is not approved for **sale** in the United States. InterMune's research programs are focused on the discovery of targeted, small-molecule therapeutics and biomarkers to treat and monitor serious pulmonary and fibrotic diseases. For additional information about InterMune and its R&D pipeline, please visit www.intermune.com.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of section 21E of the Securities Exchange Act of 1934, as amended, that reflect InterMune's judgment and involve risks and uncertainties as of the date of this release, including without limitation InterMune's expectations for the time period of the FDA's completion of its review of the NDA, the potential for pirfenidone to be approved as a medicine to treat IPF patients in the United States and InterMune's expectations regarding the timing of a potential **commercial** launch of pirfenidone in the United States. All forward-looking statements and other information included in this press release are based on information available to InterMune as of the date hereof, and InterMune assumes no obligation to update any such forward-looking statements or information. InterMune's actual results could differ materially from those described in InterMune's forward-looking statements.

Other factors that could cause or contribute to such differences include, but are not limited to, those discussed in detail under the heading "Risk Factors" in InterMune's most recent annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 24, 2014 (the "Form 10-K") and other periodic reports filed with the SEC, including but not limited to the following: (i) the risks related to the uncertain, lengthy and expensive clinical development process for the **company**'s product candidates, including having no unexpected safety, toxicology, clinical or other issues and having no unexpected clinical trial results such as unexpected new clinical data and unexpected additional analysis

of existing clinical data; (ii) risks related to the regulatory process for the **company**'s product candidates, including the possibility that the results of the new 52-week Phase 3 clinical trial (ASCEND) having an FVC endpoint may not be satisfactory to the FDA for InterMune to receive regulatory approval for pirfenidone in the United States; (iii) risks related to unexpected regulatory actions or delays, in particular in connection with our planned resubmission of a Class 2 NDA with the FDA seeking approval of pirfenidone or other government regulation generally; (iv) risks related to our ability to successfully launch and commercialize pirfenidone in the United States, if approved by the FDA and (v) InterMune's ability to obtain or maintain patent or other proprietary intellectual **property** protections. The risks and other factors discussed above should be considered only in connection with the fully discussed risks and other factors discussed in detail in the Form 10-K and InterMune's other periodic reports filed with the SEC, all of which are available via InterMune's web **site** at www.intermune.com.

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