Pierre Fabre Médicament obtains MA in China for NAVELBINE® Oral (Vinorelbine*) in the treatment of advanced lung and breast cancer

Castres, September 22, 2014 – Pierre Fabre Médicament announced that it had obtained marketing authorization (MA) in China from the CFDA (China Food and Drug Administration) for NAVELBINE® Oral in monotherapy or in association, for the treatment of locally advanced, unresectable, non-small cell lung cancer and for advanced breast cancer.

This authorization follows the filing of the registration dossier in 2010, which included the results of two randomized studies conducted by Pierre Fabre in China since 2008, the date of inclusion of the first patient. These studies, which were performed on Chinese patients, have helped to validate the interest of NAVELBINE® Oral in the first-line treatment of patients with lung cancer or metastatic breast cancer.

“The availability of oral chemotherapy in China will help facilitate out-patient care for many patients suffering from lung or breast cancer. This authorization marks an important stage in the international development of the pharmaceutical division and more particularly of its oncology franchise.” Frédéric Duchesne, President of Pierre Fabre Médicament.

The number of patients treated for cancer is growing in China, particularly due to improved screening and better patient management. Lung and breast cancers are among the main cancers affecting the Chinese population. With over 19.3 million new cancer cases each year worldwide between now and 2025**, these pathologies are a major public health burden.

About NAVELBINE®

In 1989 NAVELBINE® received marketing authorization (MA) for Europe for the indication of Non-Small Cell Lung Cancer (NSCLC). In 1991, this MA was followed by marketing authorization for the indication of metastatic breast cancer. NAVELBINE® has since been registered for NSCLC and/or breast cancer indications in over 90 countries, including the USA in 1994. In 2001 the oral form obtained MA, and this formulation is currently registered in 53 countries.

Oral chemotherapy improves out-patient care, one of the major objectives of the 2014 Cancer Plan established by the French Health Authorities. NAVELBINE® Oral offers efficacy and tolerance similar to those of the intravenous formulation with the advantages of oral administration, associated with improved comfort for the patient.

* In the form of ditartrate
About Pierre Fabre

Pierre Fabre is the third largest pharmaceutical laboratory in France. In 2013, its revenue represented over €2 billion, 56% of which came from international business. Pierre Fabre, which has always been based in the Midi-Pyrénées in southern France, has subsidiaries in 44 countries and distribution agreements in over 130 countries.

It is present in all healthcare segments; from ethical pharmaceuticals to dermo-cosmetic products, to OTC drugs. Pierre Fabre has some 10,000 employees worldwide. In 2013, the group devoted over 17% of its revenue from pharmaceuticals to R&D, based on three research priorities: oncology, dermatology and neuropsychiatry. Oncology receives 50% of the R&D investment from the pharmaceutical branch.

Through the holding company Pierre Fabre Participations, 86% of Laboratoires Pierre Fabre are held by the Pierre Fabre Foundation, recognized as a public-interest foundation since 1999. The remainder of the shares is held by the company’s employees (7%) and as treasury shares (7%).

About the Pierre Fabre Oncology Franchise

Pierre Fabre know-how in oncology stems from 25 years of experience in the discovery, development and global commercialization of innovative anti-cancer drugs, particularly plant-based cytotoxic agents (vinorelbine, vinflunine) and monoclonal antibodies. Pierre Fabre has two main laboratories devoted to oncology R&D: Pierre Fabre Research Institute (IRPF) situated on the Toulouse-Oncopole campus and the Center of Immunology Pierre Fabre (CIPF) in Saint-Julien-en-Genevois (Haute-Savoie, south-eastern France).

In February 2014, Pierre Fabre reached a key milestone in the field of immuno-oncology by entering into a licensing agreement with the Indian-based biotech company Aurigene, to develop and commercialize (outside of India) a new immune checkpoint modulator, AUNP-12, targeting the PD-1/PD-L1 pathway. Pierre Fabre recently launched several studies including a phase-III study with vinflunine in head and neck cancers, a phase-II study with a topoisomerase II inhibitor in acute myeloid leukemia and a phase-I study with anti-CXCR4 monoclonal antibodies. Furthermore, Pierre Fabre is pursuing several research programs on immunoconjugates associating antibodies with cytotoxic agents.

For further information, visit our website: www.pierre-fabre.com.

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