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FIRST PHASE II TRIAL WITH IPH2201 OPEN IN HEAD AND NECK CANCER

 First Phase II of IPH2201, a novel checkpoint inhibitor entering the immunooncology field

Marseille, France, December 19, 2014

Innate Pharma SA (the "Company" - Euronext Paris: FR0010331421 - IPH), the innate immunity company developing first-in-class therapeutic antibodies for cancer and inflammatory diseases, today announced that the first Phase II trial of IPH2201, a first-in-class NKG2A checkpoint inhibitor, was opened at the Charité Comprehensive Cancer Center (CCCC), Berlin, Germany.

IPH2201-201 is an open label Phase II trial testing IPH2201 as a single agent in a preoperative setting of squamous cell carcinoma of the oral cavity (OCSCC), a tumor type representative of the larger group of squamous cell cancer of the head and neck.

Dr Jan D Raguse, assistant medical director, Clinic for Oral & Maxillofacial Surgery, Berlin Centre of Reconstructive Surgery, CCCC, and principal investigator of the study, said: "The rationale for this trial is based on the frequent expression of the NKG2A receptor and its ligand, HLA-E, in patients with OSCC". He added: "The pre-operative setting is very appealing as the absence of prior therapy eliminates confounding effects. This design optimizes our ability to evaluate the antitumor activity of IPH2201. Access to the tumor is another key attractive feature of the study as it will allow a detailed pharmacological evaluation".

Hervé Brailly, CEO and co-founder of Innate Pharma, said: "We are very enthusiastic to start this first Phase II trial of IPH2201, a novel checkpoint inhibitor entering the immuno-oncology field. IPH2201 is exciting because it has the potential to stimulate both the innate and adaptive arms of the immune system to kill tumor cells". He added: "The CCCC is a reference cancer center with a large experience in the treatment of squamous cell cancer of the head and neck. IPH2201 will be further tested in both hematologic and solid tumors with high level of HLA-E expression".

The rationale of this trial is based on the expression of NKG2A by both NK and CD8+ cells infiltrating OCSCC (Katou, Ohtani et al. 2007). Binding of IPH2201 to NGK2A blocks the HLA-E driven inhibition of NK and CD8+ cells. HLA-E is expressed in about 80% of patients with squamous cell carcinoma of the head and neck (SSCHN) (Silva 2011; Nasman, Andersson et al. 2013). The resulting stimulation of both the innate and acquired immunity could lead to clinical and pharmacological antitumor activity. In a Phase I dose-escalation safety trial conducted by CCCC, IPH2201 appeared to have a safe and well-tolerated profile.



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About study IPH2201-201:

The primary objective of this open label Phase Ib/II trial is to evaluate the clinical and pharmacological activity of IPH2201 as a single-agent in treatment-naïve pre-operative patients with resectable intermediate or high risk (stage III-IVa) OCSCC. The secondary objectives are to assess the safety of IPH2201, the pharmacokinetics, the immunogenicity and the pharmacodynamics including intra-tumoral biomarkers.

43 patients are planned to be enrolled. The first 6 patients will receive IPH2201 at a dose of 4 mg/kg q2w x 4. Subsequent patients will be treated at a dose of 10 mg/kg q2w x 4. Based on a previous Phase I study with IPH2201, these dosages are expected to induce saturation of the NKG2A receptor. Standard loco-regional treatment with surgery followed by adjuvant therapy will be initiated after the last administration of IPH2201. Progression-free survival and survival will be assessed at 12 and 36 months after treatment administration, offering other opportunities to perform preliminary assessments of the antitumor activity.

About squamous cell carcinoma of the oral cavity (OCSCC):

Squamous carcinoma of the oral cavity (OCSCC) represents at least 25% of squamous cell cancers of the head and neck (HNSCC). They are often diagnosed at a locally advanced stage, stage III to stage IV (with a large primary tumor and/or invaded lymph nodes). For patients with locally advanced OCSCC, surgical resection remains, whenever it is feasible, the cornerstone of the treatment. The risk of loco-regional or distant relapse is however high. Preoperative chemotherapy (also called "neoadjuvant chemotherapy") has been assessed with the aim to facilitate the surgical resection and to reduce the incidence of relapses, without success. Current prognosis of locally advanced but resectable OCSCC remains poor. Around 30% of the patients relapse during the first year, and 50% during the first 2 to 3 years following the resection of the tumor, despite the adjuvant treatment. Around 20% of the patients die during the year after surgery. Five year disease-free survival (DFS) and overall survival (OS) of operated patients does not exceed 50-60% (Licitra, Grandi et al. 2003; Zhong, Zhang et al. 2013).

About IPH2201:

IPH2201 is a first-in-class immune checkpoint inhibitor targeting NKG2A receptors expressed on tumor infiltrated cytotoxic NK and CD8 T lymphocytes.

NKG2A is an inhibitory receptor binding HLA-E. By expressing HLA-E, cancer cells can protect themselves from killing by NKG2A+ immune cells. HLA-E is frequently up-regulated on cancer cells of many solid tumors or hematological malignancies. IPH2201, a humanized IgG4, blocks the inhibitory function of NKG2A. Hence, IPH2201 may re-establish a broad anti-tumor response mediated by NK and T cells. IPH2201 may also enhance the cytotoxic potential of other therapeutic antibodies.



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About Innate Pharma:

Innate Pharma S.A. is a biopharmaceutical company discovering and developing first-in-class therapeutic antibodies for the treatment of cancer and inflammatory diseases.

Its innovative approach has translated into major alliances with leaders in the biopharmaceutical industry such as Bristol-Myers Squibb and Novo Nordisk A/S.

The Company has two clinical-stage programs in immuno-oncology, a new therapeutic field that is changing cancer treatment by enhancing the capability of the body's own immune cells to recognize and kill cancer cells. Innate Pharma science also has potential in chronic inflammatory diseases.

Listed on Euronext-Paris, Innate Pharma is based in Marseille, France, and had 97 employees as at September 30, 2014.

Learn more about Innate Pharma at www.innate-pharma.com.

Practical Information about Innate Pharma shares:

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Disclaimer:

This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the *Document de Reference* prospectus filed with the AMF, which is available on the AMF website (http://www.amf-france.org) or on Innate Pharma's website.

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in Innate Pharma in any country.

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