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# PRELIMINARY DATA FROM A PHASE I DOSE ESCALATION AND EXPANSION STUDY OF MONALIZUMAB AND IMFINZI® (DURVALUMAB) SHOW ANTI-TUMOR ACTIVITY IN COLORECTAL CANCER PATIENTS

- Preliminary activity observed in patients with recurrent/metastatic microsatellite-stable colorectal cancer (MSS-CRC), a population historically unresponsive to PD-1/L1 blockade
- 3 partial responses (PR) and 11 stable disease (SD) response among 37 patients evaluable for efficacy disease control rate (DCR) at 16 weeks was 24%
- Manageable toxicity profile demonstrated
- Updated clinical data will be presented at ASCO

# Marseille, France, May 17, 2018, 07:00 AM CEST

Innate Pharma SA (the "Company" - Euronext Paris: FR0010331421 - IPH) last night announced preliminary data from an ongoing Phase I dose escalation and expansion study evaluating the safety and efficacy of the combination of monalizumab, a first-in-class monoclonal antibody targeting NK- and T cell checkpoint receptor NKG2A, with durvalumab.

Data show preliminary anti-tumor activity in patients with recurrent, metastatic colorectal cancer, with 3 partial responses and 11 stable disease responses among 37 patients evaluable for efficacy, with a disease control rate of 24% at 16 weeks (data cut as of February 8, 2018). The data also showed a manageable toxicity profile.

The Phase I dose escalation and expansion study enrolled a total of 55 patients. In the dose-escalation part, 15 patients with selected solid tumors received durvalumab 1500 mg every 4 weeks in combination with monalizumab at increasing doses. In the expansion phase, 40 patients with microsatellite-stable colorectal cancer (MSS-CRC) were enrolled. 58% of patients in expansion had 3+ lines of prior therapy.

These data were highlighted in an abstract (#3540) published online on May 16 by the American Society of Clinical Oncology (ASCO) in advance of its annual meeting in Chicago, Illinois, June 1-5, 2018. The abstract is available on the ASCO website. A poster (#33) with updated clinical data will be presented at ASCO in the Gastrointestinal (Colorectal) Cancer session in Hall A on Sunday, June 3 between 8:00am and 11:30am.

Based on these preliminary results, Innate's partner AstraZeneca/MedImmune progressed the combination with standard of care therapies.

#### **About Monalizumab:**

Monalizumab is a first-in-class antibody targeting NKG2A receptors expressed on tumor infiltrating cytotoxic NK and CD8 T lymphocytes.



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

Monalizumab with MedImmune, AstraZeneca's global biologics research and development arm, through a co-development and commercialization agreement. An exploratory joint clinical development program is ongoing, focused on investigating monalizumab in combination strategies.

#### **About Durvalumab:**

Durvalumab, a human monoclonal antibody directed against PD-L1, blocks PD-L1 interaction with PD-1 and CD80 on T cells, countering the tumor's immune-evading tactics and inducing an immune response.

As part of a broad development program, durvalumab is being investigated as monotherapy and in combination with IO, small molecules, and chemotherapies across a range of tumors and stages of disease.

## **About CRC:**

Colorectal cancer is the 3rd most commonly diagnosed cancer, with 1.65 million new cases and 835,000 deaths per year worldwide (WHO, GLOBOCAN database, 2015). 21% of colorectal cancer cases are metastatic at diagnosis, but given that some patients who are diagnosed with local disease at some point progress, the total number of patients with metastatic disease may account for roughly 50% of all colorectal cancer patients.

Despite advances in chemotherapy regimens in combination with biologics in the treatment of CRC, a significant number of patients progress within 6 months after receiving either first or second-line chemotherapy. Furthermore, among patients who are beyond second line treatment, even greater numbers progress within 6 months of their last treatment. Current investigations are now adding immunotherapeutics to chemotherapeutics to broaden antitumor responses. Initial studies with anti-PD-1 or anti-PD-L1 single-agent therapy have yielded limited to no activity in unselected patients with refractory MSS-CRC.

## About Innate Pharma:

Innate Pharma S.A. is a clinical-stage biotechnology company dedicated to improving cancer treatment and clinical outcomes for patients through first-in-class therapeutic antibodies that harness the body's own immune system.

Innate Pharma specializes in immuno-oncology, a new therapeutic field that is changing cancer treatment by mobilizing the power of the body's immune system to recognize and kill cancer cells.

The Company's broad pipeline includes four first-in-class clinical stage antibodies as well as preclinical candidates and technologies that have the potential to address a broad range of cancer indications with high unmet medical needs.



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Innate Pharma has pioneered the discovery and development of checkpoint inhibitors, with a unique expertise and understanding of Natural Killer cell biology. This innovative approach has resulted in major alliances with leaders in the biopharmaceutical industry including AstraZeneca, Bristol-Myers Squibb, Novo Nordisk A/S and Sanofi. Innate Pharma is building the foundations to become a fully-integrated biopharmaceutical company.

Based in Marseille, France, Innate Pharma has more than 180 employees and is listed on Euronext Paris.

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

# Information about Innate Pharma shares:

**ISIN code** FR0010331421

Ticker code IPI

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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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