Lipopharma presents latest results of 2OHOA study in cancer at Bio-Europe 2015

Dose-escalation part of the MIN-001-1203 clinical study completed, confirming an excellent safety profile up to very high doses and very promising anticancer activity confirmed in 4 patients, including one GBM patient with sustained and almost complete tumour regression after 26 months of treatment.

Palma de Mallorca, November 3rd, 2015. – Lipopharma presented today updated results of the ongoing Phase I/IIA clinical trial with 2OHOA in patients with advanced solid tumours, including malignant glioma (MIN-001-1203), within the next-generation presentation track at Bio-Europe 2015 in Munich.

In this pitch presentation, Vicenç Tur, Lipopharma's CEO, announced that 7 cohorts of the MIN-001-1203 study have been completed, with doses ranging from 500mg/day to 16g/day, with a total of 32 patients (12 with glioblastoma, GBM) participating in these first 7 cohorts, of which 28 have completed at least one cycle of treatment and are evaluable for safety assessment. The study drug, administered as PO suspension, 2 or 3 times daily, has been generally well tolerated up to 12 g/day, while patients have had difficulties to handle the large volume of medication required for the 16g/day (8g twice daily) dose, experiencing frequent gastrointestinal effects that in some cases were difficult to manage. No drug-related **serious adverse events (SAE)**, or other relevant **toxicity effects** associated to the investigational product have been reported in any of the 32 patients treated, other than the tolerability issues experienced at the highest dose levels (gastrointestinal effects). Two additional **safety expansion cohorts** treated with the Maximum Tolerated Dose, one with 10 glioma patients and another with 10 patients with solid biopsiable tumours, will start in about two weeks in order to evaluate the effect of 2OHOA in different biomarkers and to further explore preliminary efficacy in glioma patients.

Although this is safety study and in the dose escalation part there are no patient selection criteria with a view of exploring efficacy, **clinical benefit** has been reported in **4 patients**, 3 of them with GBM, including one GBM patient (ongoing) that has achieved a **sustained partial response (PR)** on RANO criteria (tumour shrinkage >91%) lasting now for more than **26 months**. Two other GBM patients have had Stable Disease (SD) for 6 months and a fourth patient with progressive mesothelioma had SD lasting up to cycle 15 (10 months).

Lipopharma announced also that, following the excellent results of the MIN-001-1203 PI/IIa study, the company will shortly open a new **financial round** in order to rise funds to conduct a **PIIb study** with 2OHOA in GBM which, if successful, could lead to a conditional approval in Europe for the treatment of newly-diagnosed GBM in combination with radiotherapy and temozolomide.

Bio-Europe is the most important bio-partnering event held in Europe, bringing together close to 3500 top executives from biotechnology and pharmaceutical companies, leading specialized investors and scientific thought leaders from all around the world. V. Tur and Prof. Xavier Busquets, Lipopharma SAB's president and one of the co-founders of the company, attended this year's edition of Bio-Europe in Munich with the objective of pursuing Lipopharma's ongoing contacts with key industry players, as well as to explore new additional collaborations with potential industrial partners and investors that would facilitate the development of its innovative MLT-based R&D programs.

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ADDITIONAL INFORMATION

About 2OHOA

2OHOA (2-hydroxyoleic acid) is an orally bioavailable synthetic analog of oleic acid that selectively modulates **sphingomyelin synthase (SMS) activity**, thereby increasing the concentration of sphingomyelin (**SM**), ceramide (**Cer**) and diacylglycerol (**DAG**) in the tumor cell membrane and decreasing membrane levels of phosphatidylethanolamine (PE), phosphatidylcholine (PC) and phosphatidylserine (PS). This restores the normal, healthy levels and ratios of membrane lipids, inhibiting membrane-protein associated signalling and the aberrant activity of signalling pathways in tumour cells, including the Ras/MAPK and PI3K/AKt pathways, stopping tumour cell proliferation, inducing tumour cell differentiation, and eventually causing selective cancer cell death by autophagy/apoptosis.

In pre-clinical studies this compound has demonstrated high efficacy (with no apparent toxicity) against some of the most lethal forms of cancer. Positive "proof of concept" studies of 2OHOA in animal models of human tumours of Glioma, NSCLC, Pancreas or Prostate are already available.

2OHOA has obtained the **Orphan Drug** designation by the EMA for the treatment of glioma in October 2011. A PI/IIa **clinical study** in glioma and other solid tumours (**MIN-001-1203**) is currently ongoing since May 2013, so far with very positive results.

About MLT

Membrane-Lipid Therapy (MLT) derives from a highly specialized scientific knowledge developed by Lipopharma's scientists and consists on the design of molecules that regulate the structure and functions of the membrane lipids, instead of targeting cellular proteins. This innovative know-how is Lipopharma's main expertise and lays on new discoveries made by Lipopharma's scientists related to the role of membrane lipids and membrane lipid structure on the regulation of localization and activity of membrane signalling proteins.

About Lipopharma

Lipopharma is a pioneering clinical-stage biopharmaceutical company that focuses on the discovery, design and clinical development of a new generation of medicines that act through the innovative therapeutic strategy: Membrane-Lipid Therapy (MLT). Since 2006 Lipopharma develops industrial applications of new scientific breakthroughs and discoveries patented by leading researchers at the University of the Balearic Islands (UIB).

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