

## Hybrigenics half-year 2016 financial results and pharmaceutical R&D highlights

- **EUR 1.5 million milestone achieved in the research partnership with Servier on an Ubiquitin-Specific Protease program in oncology**
- **First patients treated in France in the Phase II clinical trial of inecalcitol in Acute Myeloid Leukemia (AML)**
- **Two new patents on inecalcitol granted in the United States**
- **Authorization to launch in the US the Phase II clinical trial of inecalcitol in AML granted by the Food and Drug Administration**

**Paris, 25 October 2016** – Hybrigenics SA (ALHYG), a bio-pharmaceutical group listed on the Alternext market of Euronext in Paris, with a focus on research and development of new treatments against proliferative diseases and specialized in protein interaction and genomic services, today announces its consolidated results for the first half of 2016 ended June 30<sup>th</sup>.

EUR million	HYR 2016	HYR 2015	Growth
<b>Turnover from scientific services</b>	<b>1.7</b>	<b>1.5</b>	<b>+5%</b>
Turnover from research collaboration	-	0.4	(100%)
Other operating revenues <sup>a</sup>	1.0	0.9	+11%
<b>Total operating revenues</b>	<b>2.7</b>	<b>2.8</b>	<b>(4%)</b>
<b>Total operating costs</b>	<b>(5.6)</b>	<b>(5.6)</b>	<b>=</b>
Other operating profit/loss	-	0.4 <sup>b</sup>	(100%)
<b>Operating loss</b>	<b>(2.9)</b>	<b>(2.4)</b>	<b>(21%)</b>
Net Loss	(2.9)	(2.3)	(26%)
Net operating and investment cash burn	(3.2)	(3.0)	(10%)
Net financing cash flow	(0.1)	8.1	(100%)
<b>Cash Position (end of period)</b>	<b>8.4</b>	<b>14.8</b>	<b>(43%)</b>

<sup>a</sup>research subsidies, subleases, services to subleasers and current year research tax credit; <sup>b</sup>retrospective research tax credit for 2014

The turnover from scientific services increased to EUR 1.7 million in the first half of 2016, up 5% as compared to the first half of 2015, following the same positive trend observed at the end of full year 2015 as compared to full year 2014 (see Hybrigenics' press release of April 25, 2016).

Research funding paid by Servier accounted for EUR 0.375 million in the first half of 2015 and stopped in September 2015. However, the objectives of this research collaboration have been reached, triggering a EUR 1.5 million milestone payment by Servier, equivalent to two full years of research funding in a single instalment in the second half of 2016. Hybrigenics remains associated to the success of this program focusing on one Ubiquitin-Specific Protease in oncology for a total of up to EUR 12 million of potential additional milestone payments until registration of a drug (see Hybrigenics' press release of October 10, 2016).

Total operating costs are exactly stable at EUR 5.6 million. Operating and net losses for the first half of 2016, both equal to EUR 2.9 million, are respectively 21% and 26% higher than for the first half of 2015, mostly due to the retrospective 2014 research tax credit of EUR 0.4 million in 2015 recorded in other operating profit.

Hybrigenics' cash position as of June 30<sup>th</sup>, 2016 was EUR 8.4 million (not yet including the EUR 1.5 million milestone payment from Servier) as compared to EUR 11.7 million on December 31<sup>st</sup>, 2015 and to EUR 14.8 million on June 30<sup>th</sup>, 2015.

### **Pharmaceutical R&D highlights**

Since the beginning of 2016, Hybrigenics has been very active and successful in the United States. The authorization to perform a double-blind placebo-controlled Phase II clinical trial of inecalcitol in Acute Myeloid Leukemia (AML) was granted by the American Food and Drug Administration (FDA) in the minimum regulatory time of just one month after having filed the application. This was achieved thanks to a close working relationship with Prof. J. Cortes, Deputy Chair of the Leukemia Department, University of Texas MD Anderson Cancer Center in Houston. This collaboration has recently been nominated for the final round of the MedStartUp Awards in the "Best Collaboration with Academia Leading to a Breakthrough Solution" category.

In parallel, two American patents, one protecting a specific step in the chemical synthesis of inecalcitol and another one covering its convenient formulation as innovative tablets, have been granted by the United States Patent and Trademark Office (USPTO), meaning that Hybrigenics has the exclusive intellectual property of inecalcitol until September 10<sup>th</sup>, 2031 in this country.

In France, Hybrigenics has implemented the same clinical study in AML under the same FDA-approved protocol and enrolled its first patients since September. In addition, as already mentioned, the objectives of the research collaboration with Servier on a Ubiquitin-Specific Protease (USP) relevant to oncology have been met.

*"Besides a satisfactory constant organic growth of our services business, our pharmaceutical R&D activities achieved major goals in the past nine months. A EUR 1.5 million milestone was obtained in the research partnership with Servier. We have organized the US landing of our clinical operations and secured additional new American intellectual property protecting inecalcitol until 2031. Last but not least, the first French patients of the Phase II clinical trial of inecalcitol in Acute Myeloid Leukemia have started their treatment. These achievements are the results of a strategy emphasizing pharmaceutical R&D with a focus towards the United States,"* said Remi Delansorne, Hybrigenics' CEO.

### **About Hybrigenics**

Hybrigenics ([www.hybrigenics.com](http://www.hybrigenics.com)) is a bio-pharmaceutical group listed (ALHYG) on the Alternext market of Euronext Paris, focusing its internal R&D programs on innovative targets and therapies for the treatment of proliferative diseases.

Hybrigenics' development program is based on inecalcitol, a vitamin D receptor agonist active by oral administration. Oral inecalcitol has shown excellent tolerance and strong presumption of efficacy for the first-line treatment of metastatic castrate-resistant prostate cancer in combination with Taxotere<sup>®</sup>, which is the current gold-standard chemotherapeutic treatment for this indication. Inecalcitol has also been tested in chronic lymphocytic leukemia patients, an indication for which inecalcitol has received orphan drug status in Europe and the United States. Two clinical Phase II studies of inecalcitol are currently ongoing in chronic myeloid leukemia and acute myeloid leukemia.

Hybrigenics' research program is exploring the role of enzymes called Ubiquitin-Specific Proteases (USP) in the balance between degradation and recycling of proteins called onco-proteins due to their involvement in various cancers. Hybrigenics is also evaluating the interest of inhibitors of USP as anti-cancer drug candidates. Hybrigenics has collaborated with Servier on one particular USP in oncology. In this R&D program, two steps have been reached and additional milestones may be achieved until registration of a potential drug.

# HYBRIGENICS

## Press Release

Hybrigenics Services ([www.hybrigenics-services.com](http://www.hybrigenics-services.com)) is the market leader in Yeast Two-Hybrid (Y2H) and related services to identify, validate and inhibit protein interactions for researchers in all areas of life sciences, using its ISO 9001-certified high-throughput Y2H screening platform.

Helixio ([www.helixio.com](http://www.helixio.com)), Hybrigenics' genomic branch, provides state-of-the-art services specialized in DNA chips, DNA or RNA target enrichment and next generation sequencing with an Illumina NextSeq500.

Hybrigenics Corp., based in Cambridge, Mass., is the American subsidiary of Hybrigenics.

\*\*\*

**HYBRIGENICS is listed on the Alternext market of Euronext Paris**

**ISIN: FR0004153930**

**Ticker: ALHYG**



**Hybrigenics**

Rémi Delansorne

CEO

Tel.: +33 (0)1 58 10 38 00

[investors@hybrigenics.com](mailto:investors@hybrigenics.com)

**NewCap**

Financial communication

Julien Perez / Pierre Laurent

Tel.: +33 (0)1 44 71 94 94

[hybrigenics@newcap.eu](mailto:hybrigenics@newcap.eu)