



## ABIVAX REPORTS 2020 FINANCIAL RESULTS AND OPERATIONS UPDATE

- Recruitment completed in ABX464 phase 2b ulcerative colitis and phase 2a rheumatoid arthritis studies; top-line results for both studies will become available in Q2 2021
- Excellent short- and long-term efficacy and safety data for 50 mg once-daily oral ABX464 in ulcerative colitis phase 2a study published in “Gastroenterology”
- Recruitment for dose escalation phase of ABX196 proof-of-concept study in hepatocellular carcinoma to be completed shortly, with top-line data expected in Q2 2021
- The Bpifrance funded Covid-19 trial was stopped due to lack of efficacy, however, good safety and tolerability profile of ABX464 confirmed
- Funding raised in 2020 amounts to EUR 84M, incl. an oversubscribed EUR 28M capital increase at market price, EUR 36M Bpifrance financing, EUR 15M straight loan by Kreos Capital and EUR 5M state-guaranteed loan by Société Générale
  - Cash resources fund operations through Q4 2021

**PARIS, France, March 31, 2021 – 06:00 p.m. (CET)** – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, today announced its 2020 annual financial results, as of December 31, 2020, and provides an update on the progress of its product pipeline. The financial statements for 2020, approved by the Company’s Board of Directors on March 30, 2021, have been audited and the certification report is being prepared by the Company’s external auditors.

*“2020 was a very successful year for Abivax as we substantially advanced the late-stage clinical development for our core clinical program in chronic inflammatory diseases. Abivax reached several important milestones in 2020 despite the challenges of the Covid-19 pandemic. We confirmed the long-term safety and efficacy of ABX464 in ulcerative colitis patients in our two-year phase 2a maintenance study. Patient recruitment was completed for the phase 2b study of ABX464 to treat ulcerative colitis in December 2020, and for the phase 2a study in rheumatoid arthritis in February of this year. We look forward to bringing ABX464 into a global phase 3 clinical program in UC later this year. We also plan to initiate execution of a phase 2b/3 study to treat Crohn’s disease in 2021, consistent with our development strategy in inflammatory bowel diseases.”, said Prof. Hartmut Ehrlich, M.D., CEO of Abivax. “Our second compound, ABX196 for hepatocellular carcinoma, also made progress in phase 1/2 clinical testing in the US. The recruitment of liver cancer patients for the dose escalation phase will be completed shortly and the results will become available in Q2 2021. Although we recently stopped the phase 2b/3 clinical trial with ABX464 in acute Covid-19 for lack of efficacy, the generated data underpin the favorable safety and tolerability profile of ABX464 and are very valuable for our inflammation program. The lack of efficacy of ABX464 in the hyper-acute setting, characterized by cytokine storm and ARDS in severe Covid-19, has no bearing on our IBD program, as the molecule has clearly demonstrated efficacy and safety in controlling chronic intestinal inflammation. Abivax is looking forward to establishing ABX464 as a novel, safe and well-tolerated oral long-term treatment option for the many patients suffering from chronic inflammatory diseases.”*

**Didier Blondel, CFO of Abivax, added:** *“Abivax successfully secured EUR 84M major financing in 2020. With our current and available cash resources, our operations are fully funded through Q4 2021. In the*

months to come, Abivax will focus on advancing its clinical late-stage core program with ABX464 in ulcerative colitis, Crohn's disease as well as rheumatoid arthritis. The expected clinical read-outs in Q2 2021, will give us more visibility on the strategic possibilities for the Company and we will carefully evaluate and select the most attractive options to create shareholder value. Our priority remains partnering with a large pharma or biotech company in the short term, once the UC phase 2b data are available."

## 2020 Financial Highlights

| Items in the Income Statement<br><i>in millions of Euros</i> | FY 2020       | FY 2019       | Change       |
|--|---------------|---------------|--------------|
| Total operating income                                       | 1.7           | 0.0           | 1.6          |
| Total operating expenses                                     | (39.7)        | (33.3)        | (6.4)        |
| <i>of which Research and Development costs</i>               | (34.5)        | (29.0)        | (5.5)        |
| <i>of which administrative costs and overheads</i>           | (5.1)         | (4.3)         | (0.8)        |
| <b>Operating result</b>                                      | <b>(38.0)</b> | <b>(33.3)</b> | <b>(4.7)</b> |
| Financial result   | (2.3)         | (1.7)         | (0.7)        |
| <b>Ordinary result</b>                                       | <b>(40.3)</b> | <b>(35.0)</b> | <b>(5.4)</b> |
| Extraordinary result   | 0.2           | 0.1           | 0.1          |
| Tax on income  | 2.6           | 4.2           | (1.6)        |
| <b>Result for the period</b>                                 | <b>(37.6)</b> | <b>(30.6)</b> | <b>(6.9)</b> |

| Financial Items from the Balance Sheet<br><i>in millions of Euros</i>                            | 31/12/2020   | 31/12/2019    | Change       |
|--|--------------|---------------|--------------|
| <b>Net financial position</b>  | <b>(4.7)</b> | <b>(11.0)</b> | <b>6.3</b>   |
| of which financial fixed assets*   | 0.0          | 0.0           | 0.0          |
| of which fixed-term deposits (maturing in > 1 year)  | 0.0          | 0.0           | 0.0          |
| of which fixed-term deposits (maturing in < 1 year)  | 0.0          | 0.0           | 0.0          |
| of which available cash  | 29.3         | 9.8           | 19.5         |
| of which financial debts   | (34.0)       | (20.7)        | (13.2)       |
| <b>Total Assets</b>  | <b>71.3</b>  | <b>51.7</b>   | <b>19.6</b>  |
| <b>Total Equity</b>  | <b>17.9</b>  | <b>18.6</b>   | <b>(0.7)</b> |
| of which equity capital  | 4.7          | 11.8          | (7.1)        |
| of which conditional advances  | 13.2         | 6.8           | 6.4          |
| * Excluding items of the liquidity contract (liquidity and own shares) and deposits & guarantees |              |               |              |

- Operating loss EUR -38.0M (EUR -4.7M compared to EUR -33.3M as of December 31, 2019) mainly reflects the increasing investments in R&D (+EUR 5.5M)
- Total number of employees at the end of December 2020 was steady at 27
- R&D expenses amounted to EUR 34.5M, mainly due to increasing funding needs of the development of ABX464 in inflammatory indications (95% of the total R&D expenses)
- G&A expenses were at EUR 5.1M in 2020 and stayed proportionally stable compared to 2019 with EUR 4.3M (13% of total operating costs)



- Revenue comprised EUR 1.6M grant portion of the first Bpifrance Covid-19 funding paid in June 2020. Income also included a EUR 2.6M R&D tax credit in 2020 (EUR 4.2M in 2019)
- The company's cash utilization rate during 2020 was EUR 3.3M per month
- Abivax secured in total EUR 84M funding in 2020:
  - Successfully completed an oversubscribed capital increase of EUR 28M at market price in October 2020
  - Public funding by Bpifrance of EUR 36M (EUR 20M grant and EUR 16M loan), for which the first payment milestone of EUR 14.4M has been achieved in June 2020
  - EUR 15M straight loan from Kreos Capital in October 2020
  - EUR 5M State Guaranteed loan by Société Générale in June 2020
- Cash at the end of 2020 was EUR 29.3M, compared to EUR 9.8M at the end of 2019
- The Company is funded through Q4 2021, based on the following assumptions:
  - Assessment of planned R&D needs to be substantially increased in 2021
  - 2021 opening cash
  - Exercise of the remaining equity line with Kepler Cheuvreux corresponding to the issuance of a maximum of 612,000 new shares
  - Remainder of Bpifrance Covid-19 funding, to be received despite the stop of miR-AGE study on March 5, 2021
  - 2021 cash in resulting from the reimbursement from the 2020 Research Tax Credit

## Operating Highlights: Portfolio Update

### ABX464 in ulcerative colitis (UC)

Abivax [reported excellent two-year safety and efficacy data](#) from the ABX464 UC phase 2a maintenance study in September 2020. These results confirmed the good safety profile and durable efficacy of 50 mg once-daily oral ABX464 in patients with moderate-to-severe UC. After the second year of treatment, 69% of patients were in clinical remission and 94% benefited from a clinical response. Furthermore, blinded readings of the endoscopies were performed centrally by independent reviewers. Median fecal calprotectin, the key biological marker of UC disease activity, remained at 31.6 µg/g (normal levels are below 50 µg/g).

The induction and long-term data generated with ABX464 during the phase 2a clinical trials in UC were published in a peer-reviewed article in March 2021 in the [renowned journal "Gastroenterology"](#)<sup>1</sup>.

Abivax's phase 2b study with ABX464, ABX464-103, in patients with moderate-to-severe UC is ongoing. The recruitment of 254 patients within the induction study was achieved in December 2020. Patients who completed the ABX464-103 trial had the option to continue their treatment in the corresponding open-label maintenance study ABX464-104 for up to two years to confirm the long-term safety and efficacy profile of ABX464. The phase 2b induction and maintenance studies are conducted in over 130 study centers in 15 European countries, Canada and the US. Top-line results after the induction treatment will become available in Q2 2021.

At present, more than 800 patients have been treated with ABX464 across different indications, including UC patients, some of whom are in their fourth year of continuous daily dosing.

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<sup>1</sup> Vermeire S, Hébuterne X, Tilg H, De Hertogh G, Gineste P, Steens J-M, on behalf on the ABX464 Investigators, Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial, *Gastroenterology* (2021), [doi: https://doi.org/10.1053/j.gastro.2021.02.054](https://doi.org/10.1053/j.gastro.2021.02.054).



To date, once daily oral ABX464 has a very good clinical safety and tolerability profile including evidence of short- and long-term efficacy in the treatment of UC patients. Abivax is preparing to start its clinical phase 3 program in UC by year end.

#### **ABX464 in rheumatoid arthritis (RA)**

The recruitment of 60 patients in the ABX464-301 phase 2a study in moderate-to-severe active RA was achieved in February 2021. Patients who completed the induction study could transition to the one-year open-label maintenance study, ABX464-302, to evaluate the long-term safety and efficacy of ABX464 in RA.

The phase 2a study is designed to evaluate the safety, tolerability, and preliminary efficacy of two oral dose-levels of ABX464 administered daily, in combination with methotrexate (MTX), for RA patients who had an inadequate response to either MTX and/or anti-tumor necrosis factor alpha (TNF $\alpha$ ) biological therapeutics. The trial is being conducted in 24 study centers across five European countries. Top-line data after 3 months of induction treatment will become available in Q2 2021.

Abivax is preparing to start a clinical phase 2b program in RA in early 2022.

#### **ABX464 in Crohn's disease (CD)**

Following the very promising results of the phase 2a induction and maintenance studies in UC, Abivax's IBD steering committee recommended skipping a phase 2a proof-of-concept study in CD, due to the pathophysiological and clinical similarities of CD and UC. Abivax is planning to directly initiate a phase 2b/3 study in CD with the objective to demonstrate a similar strong efficacy and favorable safety as already reported in UC. The inclusion of the first patient into this study is planned for the second half of 2021.

#### **ABX464 market potential in inflammatory diseases**

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. According to recent statistics, there were an estimated 3.5M diagnosed cases of UC in G7 countries (US, France, Germany, Italy, Spain, UK and Japan) in 2020. This represents a potential market opportunity of up to USD 6.2B annually, based on 2020 pharmaceutical sales estimates in these countries for UC only. For IBD (UC and CD), these sales have reached about USD 17.7B in 2020 and are estimated to grow to USD 24.4B in 2025, i.e. the year ABX464 is expected to reach the market. There were approximately 3.8M diagnosed cases of RA in G7 countries in 2020, representing a market potential of about USD 20.2B.

The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of USD 90B.<sup>2</sup>

Abivax's mission for ABX464 is to offer a new therapeutic option to patients suffering from chronic inflammatory diseases with improved short- and long-term efficacy and good safety.

Abivax's strategy is to develop ABX464 in inflammatory bowel diseases (UC and CD) and expand the clinical program to further chronic inflammatory indications, including RA.

ABX464 has the potential to take a substantial commercial market share in the IBD field.

#### **ABX196 in hepatocellular carcinoma (HCC)**

The phase 1/2 clinical trial in HCC is ongoing at the Scripps MD Anderson Cancer Center in San Diego and the MD Anderson Cancer Center in Houston. In this proof-of-concept study, patients who are failing on checkpoint inhibitors are treated with ABX196 in combination with nivolumab (Opdivo<sup>®</sup>,

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<sup>2</sup> Source: Informa



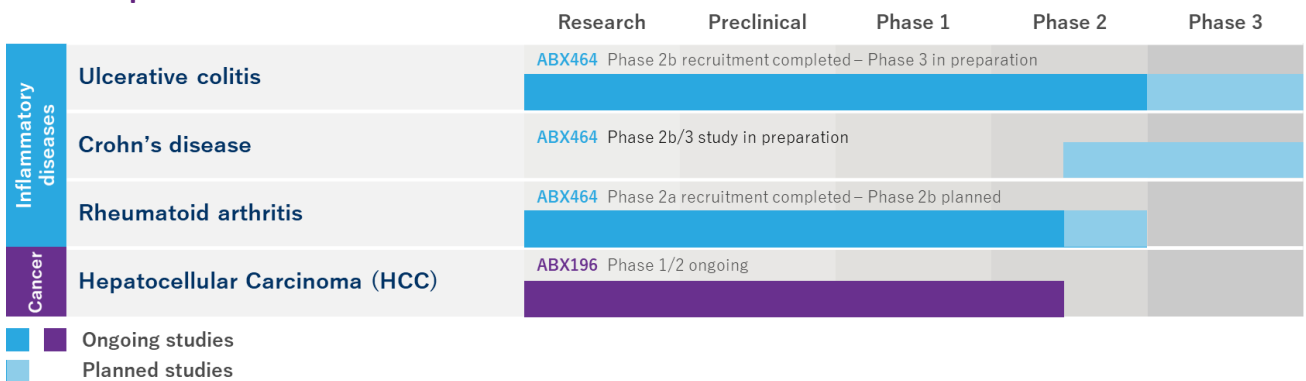
Bristol Myers Squibb). The clinical study consists of two phases, a dose escalation phase, and a subsequent expansion phase.

The patient recruitment within the dose escalation phase will be completed shortly, with top-line data in Q2 2021. The most efficient and well-tolerated dose of ABX196 will be defined and applied to the follow-on expansion phase, to be started in Q3 2021.

### Stopping of ABX464 in Covid-19 – miR-AGE trial

On March 5, 2021, Abivax [announced it would be stopping the phase 2b/3 Covid-19 study](#) (miR-AGE trial - ABX464-401) due to lack of efficacy. This decision followed the recommendation of the Data Safety and Monitoring Board (DSMB), based on an interim analysis evaluating data of 305 high-risk Covid-19 patients after they completed the 28-days study period.

### Abivax Pipeline



### Financial Calendar 2021

- **April 30, 2021: Publication and release of the 2020 annual financial report and the Universal Registration Document**
- **June 4, 2021 – 10.00 a.m.: Shareholder meeting**
- **September 23, 2021: Publication of financial statements as of June 30, 2021**
- **September 30, 2021: Publication and release of 2021 half year report**

### About Abivax ([www.abivax.com](http://www.abivax.com))

Abivax, a clinical stage biotechnology company, is developing novel therapies that modulate the body’s natural immune machinery to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, ABX464 to treat severe inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at [www.abivax.com](http://www.abivax.com). Follow us on Twitter @ABIVAX\_.



## Contacts

### **Abivax Finance**

Didier Blondel  
[didier.blondel@abivax.com](mailto:didier.blondel@abivax.com)  
+33 1 53 83 08 41

### **Abivax Communications**

Regina Jehle  
[regina.jehle@abivax.com](mailto:regina.jehle@abivax.com)  
+33 6 24 50 69 63

### **Investors LifeSci Advisors**

Chris Maggos  
[chris@lifesciadvisors.com](mailto:chris@lifesciadvisors.com)  
+41 79 367 6254

### **Press Relations & Investors Europe MC Services AG**

Anne Hennecke  
[anne.hennecke@mc-services.eu](mailto:anne.hennecke@mc-services.eu)  
+49 211 529 252 22

### **Public Relations France Actifin**

Ghislaine Gasparetto  
[ggasparetto@actifin.fr](mailto:ggasparetto@actifin.fr)  
+33 1 56 88 11 22

### **Public Relations USA Rooney Partners LLC**

Marion Janic  
[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)  
+1 212 223 4017

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