May 11, 2020

# CymaBay Reports First Quarter 2020 Financial Results and Provides Corporate Update

*Independent expert panel unanimously concludes there is no clinical, biochemical or histological evidence of seladelpar-induced liver injury in the Phase 2b NASH study*

*Panel unanimously supports re-initiating clinical development of seladelpar pending approval by the FDA*

*CymaBay plans to re-engage with the FDA as quickly as possible*

*Company remains focused on cost containment as it pursues next steps for seladelpar and continued evaluation of strategic alternatives*

*Conference call and webcast today at 4:30 p.m. ET*

NEWARK, Calif., May 11, 2020 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced corporate updates and financial results for the first quarter ended March 31, 2020.

Sujal Shah, President and CEO of CymaBay, stated, “Last week a panel of some of the most experienced and distinguished liver pathologists and hepatologists in the world completed an independent review analyzing findings from our Phase 2b study of seladelpar in patients with NASH. I am pleased to report that the panel unanimously concluded there was no clinical, biochemical or histological evidence of seladelpar-induced liver injury in the study, and as a result they also unanimously supported the lifting of the clinical hold and re-initiation of clinical development.

While we have not yet discussed full results from our investigation nor any of the panel’s conclusions with the FDA, we are planning to re-engage with the agency as quickly as possible. At this point we cannot guarantee what the next steps or timelines will be, but we are confident that we have conducted a truly rigorous, independent review to help us definitively support the conclusion that seladelpar did not cause drug-induced liver injury in our NASH phase 2b study.”

Dr. Paul Watkins, Howard Q Ferguson Distinguished Professor, Schools of Medicine, Pharmacy, and Public Health, Director, Institute for Drug Safety Sciences at the University of North Carolina, Chapel Hill, said, “I was pleased to chair this esteemed independent panel of liver experts. The panel conducted a comprehensive, systematic review and discussion of all of the clinicopathological data from the seladelpar NASH Phase 2b study. In my experience, no other drug in development for NASH has been through such rigorous scrutiny of safety data at this stage of development. As we have stated, the features noted by study pathologists at end of treatment were confirmed on this review. However, these did not differ

qualitatively between baseline and end of treatment. We suspect these histologic features are underreported; however, in the experience of the pathology review subcommittee, these features may be observed in patients with NASH. The panel unanimously concluded that the data in aggregate, including the lack of significant differences in histologic features or their changes across the placebo and treatment groups, do not support injury related to seladelpar."

Dr. Stephen Harrison, Medical Director, Pinnacle Clinical Research, Visiting Professor of Hepatology at Radcliffe Department of Medicine, University of Oxford, and principal investigator of the seladelpar Phase 2b study in NASH, added, "I believe CymaBay and the FDA did the right thing in putting patient safety first when development of seladelpar was halted at the end of last year until an in-depth investigation was conducted into the findings identified by study pathologists in the NASH study. At this point, the findings and additional data collected have been thoroughly investigated by leading experts in the areas of drug-induced liver injury and hepatopathology. Given the benefit observed on both NASH resolution and fibrosis with seladelpar in the NASH Phase 2b study as well as data presented at multiple medical meetings from studies of seladelpar in PBC, I am pleased that the independent review panel is supportive of restarting clinical development pending approval from the FDA."

**Recent Corporate Highlights**

- At the end of last week, a panel of eight of the world's foremost expert liver pathologists and hepatologists, whose collective experience relevant to CymaBay's investigation includes drug-induced liver injury, NASH and cholestatic liver diseases, completed a four-day independent review analyzing findings from CymaBay's NASH Phase 2b study. The panel unanimously supported lifting the clinical hold for seladelpar and re-initiation of clinical development. In addition to the chair, Dr. Paul Watkins, the panel included:
  ° Pierre Bedossa, MD, PhD, Professor of Pathology at the University Paris-Diderot, France, and Medical Director and CEO of LIVERPAT
  ° Michael Charlton, MD, Chief of Hepatology, Director of the Center for Liver Diseases and Medical Director of the Transplant Institute at the University of Chicago
  ° Zachary Goodman, MD, PhD, Director of Hepatic Pathology Consultation and Research, Center for Liver Disease, Inova Healthcare Services
  ° Neil Kaplowitz, MD, Professor of Medicine and Thomas H. Brem Chair in Medicine, Budnick Chair of Liver Disease, Keck School of Medicine, University of Southern California
  ° David Kleiner, MD, PhD, Head of Histopathology and Autopsy Pathology at the NIH and the Reference Pathologist for the Drug-Induced Liver Injury Network
  ° Willis Maddrey, MD, Professor Emeritus of Internal Medicine at The University of Texas Southwestern Medical Center
  ° John Vierling, MD, Professor of Medicine and Surgery, Baylor College of Medicine

- CymaBay intends to reach out to the FDA to discuss all of the data it has collected to date and the results of the panel review meetings. Once initial feedback is gathered, CymaBay intends to submit a complete response to the seladelpar clinical hold to the FDA. The CymaBay Board of Directors has worked closely with management throughout the investigation and panel review and is in support of next steps to re-

engage with the FDA.

- As a reminder, during the fourth quarter of 2019, management implemented a restructuring program following the placement of the seladelpar program on clinical hold pending further investigation of the histologic observations noted by study pathologists in CymaBay's Phase 2b NASH study and pending completion of its review of strategic options.

- Late in the first quarter of 2020, the need for sustained cost containment was further underscored by the unexpected and rapid onset of the coronavirus pandemic and the associated travel restrictions and shelter-in-place orders issued by governmental authorities in jurisdictions where CymaBay, its partners, investigators, and vendors, conduct operations. In response to these measures, CymaBay has taken steps, such as enabling remote operations for all employees, which have allowed operating activities to continue as seamlessly as possible.

- CymaBay will continue to closely monitor pandemic developments and their associated risks to the business, and will take actions available to mitigate them where possible. Further, all of CymaBay's actions will be guided by a commitment to taking all steps possible to ensure the health and safety of its employees.

- Held $176.2 million in cash, cash equivalents and short-term investments at March 31, 2020.

Mr. Shah continued, "As the next steps in our seladelpar investigation process become clear we will continue to keep our shareholders updated as appropriate, while also continuing to evaluate potential strategic alternatives. Further, we remain focused on cost containment and will look at additional steps we can take into fiscal year 2020 in order to closely control the Company's operating expenses and associated cash burn."

**First Quarter Ended March 31, 2020 Financial Results**

- Research and development expenses for the three months ended March 31, 2020 were $9.5 million, compared to $18.6 million for the three months ended March 31, 2019. Research and development expense in the first quarter of 2020 was significantly lower than the corresponding period in 2019 primarily due to declining clinical trial activities related to the Phase 3 PBC, Phase 2b NASH, and Phase 2 PSC clinical trials, and other studies, as efforts continue to scale back and shut down these studies as a result of the clinical hold on the seladelpar development program.

- General and administrative expenses for the three months ended March 31, 2020 were $4.3 million, compared to $5.7 million for the three months ended March 31, 2019. General and administrative expenses in the first quarter of 2020 was lower than the corresponding period in 2019 due to lower continuing labor costs and other administrative expenses following restructuring efforts undertaken in the fourth quarter of 2019.

- Net loss for the three months ended March 31, 2020 was $13.1 million, or ($0.19) per diluted share, compared to a net loss of $23.1 million, or ($0.37) per diluted share in

the three months ended March 31, 2019. Net loss was lower in the first quarter of 2020 compared to the corresponding period in 2019 primarily due to a decrease in operating expenses, including clinical trial and labor related expenses.

**Conference Call Details**

CymaBay will host a conference call today at 4:30 p.m. ET to discuss first quarter 2020 financial results and provide a corporate update. To access the live conference call, please dial 855-327-6837 from the U.S. and Canada, or 631-891-4304 internationally, Conference ID# 10009543. To access the live and subsequently archived webcast of the conference call, go to the Investors section of the company's website at http://ir.cymabay.com/events.

**About CymaBay**
CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need.

**Cautionary Statements**
The statements in this press release regarding the timing of completion and outcome of the investigation into the seladelpar histological findings, the potential benefits of seladelpar to patients with NASH, CymaBay's expectations and plans regarding its intended future interactions with the FDA, its current and future clinical trials and CymaBay's ability to fund current and planned clinical trials are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of seladelpar could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, risks related to: the seladelpar histological findings have not yet been submitted to the FDA, and there is no guarantee as to how or when the FDA will respond; the success, cost and timing of any of CymaBay's product development activities, including clinical trials; effects observed in trials to date that may not be repeated in the future; any delays or inability to obtain or maintain regulatory approval of CymaBay's product candidates in the United States or worldwide; and the ability of CymaBay to obtain sufficient financing to complete development, regulatory approval and commercialization of its product candidates in the United States and worldwide or to potentially restart clinical trials. Additional risks relating to CymaBay are contained in CymaBay's filings with the Securities and Exchange Commission, including without limitation its most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

**Important Information**
CymaBay Therapeutics, Inc. filed a preliminary proxy statement with the Securities and Exchange Commission (the "SEC") on May 5, 2020, and intends to file a definitive proxy statement and associated WHITE proxy card with the SEC in connection with the solicitation of proxies for CymaBay's 2020 Annual Meeting of Stockholders (the "2020 Annual Meeting"). Any definitive proxy statement and WHITE proxy card will be mailed to CymaBay's stockholders. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF CYMABAY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING CYMABAY'S PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and stockholders can obtain a copy of the relevant documents filed by CymaBay with the SEC,

including the definitive proxy statement, when it becomes available, free of charge by visiting the SEC's website, www.sec.gov. Investors and stockholders can also obtain, without charge, a copy of the definitive proxy statement, when available, and other relevant filed documents at https://ir.cymabay.com/all-sec-filings.

**Participants in the Solicitation**

CymaBay, its directors and certain of its executive officers will be deemed participants in the solicitation of proxies from stockholders in respect of the 2020 Annual Meeting. Information regarding the names of CymaBay's directors and executive officers and their respective interests in CymaBay by security holdings or otherwise is set forth in CymaBay's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020, Amendment No.1 to CymaBay's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on April 29, 2020 and CymaBay's preliminary proxy statement for the 2020 Annual Meeting of Stockholders, filed with the SEC on May 5, 2020. All such information will be contained in the definitive proxy statement and related materials that CymaBay will mail to CymaBay's stockholders in connection with the 2020 Annual Meeting of Stockholders. These documents can be obtained free of charge from the sources indicated above.

For additional information about CymaBay visitwww.cymabay.com.

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**CymaBay Therapeutics, Inc.**
**Financial Results**
*(In thousands, except share and per share information)*

| | Quarter Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| | **(unaudited)** | **(unaudited)** |
| Operating expenses: | | |
| Research and development | $ 9,509 | $ 18,588 |
| General and administrative | 4,347 | 5,663 |
| Restructuring charges | 71 | - |
| Total operating expenses | 13,927 | 24,251 |
| Loss from operations | (13,927) | (24,251) |
| Other income (expense): | | |
| Interest income | 839 | 1,176 |
| Total other income (expense) | 839 | 1,176 |
| Net loss | $ (13,088) | $ (23,075) |
| Basic net loss per common share | $ (0.19) | $ (0.37) |
| Diluted net loss per common share | $ (0.19) | $ (0.37) |
| Weighted average common shares outstanding used to calculate basic net loss per common share | 68,882,459 | 61,890,632 |
| Weighted average common shares outstanding used to calculate diluted net loss per common share | 68,882,459 | 61,890,632 |

**CymaBay Therapeutics, Inc.**
**Balance Sheet Data**
(In thousands)

| | **March 31, 2020** | **December 31, 2019** |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 176,232 | $ 190,945 |
| Working capital | 174,027 | 185,287 |
| Total assets | 188,600 | 205,727 |
| Total liabilities | 13,552 | 19,379 |
| Common stock and additional paid-in capital | 814,138 | 812,140 |
| Total stockholders' equity | 175,048 | 186,348 |

Source: CymaBay Therapeutics, Inc.