



CellMax Life and Sebela Pharmaceuticals Enter Strategic Development and Commercialization Partnership for FirstSight™ Blood Test for Detection of Colorectal Cancer and Pre-Cancer

CellMax Life closes Series C financing to accelerate development and regulatory approvals of FirstSight

SUNNYVALE, Calif. and ROSWELL, Ga. (March 23, 2021) – [CellMax Life](#), a molecular diagnostics company with proprietary technology for pre-cancer and cancer detection blood tests, and [Sebela Pharmaceuticals](#), a market leader in gastroenterology, announce the closing of a strategic development and commercial collaboration agreement, as well as CellMax's Series C financing. Participation in the financing also includes a strategic investment from new investor, Aflac Ventures, the corporate venture arm of Aflac Incorporated (NYSE: AFL), and existing investor, [ArtimanVentures](#).

"Strategic financing from market leaders, Sebela and Aflac Ventures, is a testament to CellMax's technology and vision," said Atul Sharan, chief executive officer, CellMax Life. "Sebela has a leading market position in the gastroenterology field in the United States. The financing will bring to life our vision of detecting colon cancer before it occurs through a globally marketed blood test that can detect pre-cancerous polyps."

The Series C financing will be used to accelerate the clinical development of CellMax's multimodal liquid biopsy test, FirstSight™, for the detection of colorectal cancer and pre-cancerous polyps, also known as advanced adenomas. CellMax recently initiated a multicenter U.S. study to further optimize its proprietary algorithm and cell capture techniques. CellMax and Sebela will collaborate on completing the development of FirstSight and, following approval from the U.S. Food and Drug Administration, Sebela will commercialize the test in the United States.

"For the last several years, we have closely followed the industry's development of colorectal cancer liquid biopsies," said Alan Cooke, chief executive officer, Sebela Pharmaceuticals. "Sebela and our subsidiary, Braintree, have worked with gastroenterologists for over 35 years, and we expect FirstSight to play a central role in the future of colorectal cancer screening. FirstSight may not only enable the U.S. to exceed its 80% screening rate target, as set by the National Colorectal Cancer

Roundtable, but can also help detect pre-cancerous adenomas early, referring patients to colonoscopy for preemptive removal.”

This partnership complements Sebela’s portfolio of market-leading gastroenterology and colonoscopy preparation products, which are utilized to facilitate colonoscopies, the “gold standard” for the prevention and detection of colorectal cancer. Colonoscopies remain the only means of removing detected pre-cancerous lesions to prevent colorectal cancer.

At the 2021 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancer Symposium, Dr. Shai Friedland, professor of medicine at Stanford University Medical Center and chief of gastroenterology at the VA Palo Alto Health Care System, presented [results](#) from a prospective study performed on 458 subjects utilizing FirstSight, a multimodal assay comprised of circulating dysplastic epithelial cells and circulating tumor DNA mutation markers, in combination with a proprietary algorithm.

“A test that detects only colorectal cancer, and not adenomas, will result in missed opportunities to prevent cancer and subject patients to invasive cancer treatments,” said Dr. Friedland. “Today, there is not a single non-invasive screening test that can accurately detect pre-cancerous polyps even nearly as effective as a colonoscopy. Our study data with the FirstSight blood test continues to show consistent ability to detect advanced adenomas with high sensitivity, enabling removal before they progress to carcinomas.”

In clinical studies performed in the U.S. and Taiwan, FirstSight has demonstrated strong performance in detecting both advanced adenomas and colorectal cancer. FirstSight has also shown the ability to detect recurrent neoplasia following polypectomy.^{i-v}

Colorectal cancer represents the second deadliest cancer in the U.S., despite being one of the most preventable.^{vi} Additionally, screening adherence rates have fallen short of the 80% target, as only 68.8% of adults aged 50 to 75 years, and only 63.3% of adults aged 50 to 64 years, were up to date with colorectal cancer screening as of 2018.^{vii}

About CellMax Life

CellMax Life is a diagnostics company focused on cancer screening with proprietary technology for detecting precancerous and cancer cells and genomic aberrations in a single blood sample. CellMax Life is headquartered in Sunnyvale, California, and has a CLIA certified and CAP accredited laboratory at this location. For more information, visit <http://www.cellmaxlife.com>.

About Sebela Pharmaceuticals®

Sebela Pharmaceuticals is a growth-oriented pharmaceutical company focused in gastroenterology, colorectal cancer detection and prevention. Braintree, a part of Sebela Pharmaceuticals, is a pioneer in colonoscopy screening with a broad marketed portfolio of innovative prescription colonoscopy preparations and gastroenterology products. Braintree has multiple clinical development programs including, in

collaboration with Cellmax Life, a multimodal liquid biopsy test, FirstSight™, for the detection of colorectal cancer and pre-cancerous polyps. Sebela's core therapeutic areas also include women's health and dermatology. In women's health, Sebela has two next generation intra-uterine devices (IUDs) for contraception in late-stage clinical development. Sebela Pharmaceuticals has offices in Roswell, GA; Braintree, MA; and Dublin, Ireland; has annual net sales of \$200-250 million; and has grown to over 300 employees through strategic acquisitions and organic growth. Please visit sebelapharma.com for more information.

About Aflac Incorporated

Aflac Incorporated (NYSE: AFL) is a Fortune 500 company helping provide protection to more than 50 million people through its subsidiaries in Japan and the U.S., where it is a leading supplemental insurer by paying cash fast when policyholders get sick or injured. For more than six decades, insurance policies of Aflac Incorporated's subsidiaries have given policyholders the opportunity to focus on recovery, not financial stress. Aflac Life Insurance Japan is the leading provider of medical and cancer insurance in Japan where it insures 1 in 4 households. For 15 consecutive years, Aflac Incorporated has been recognized by Ethisphere as one of the World's Most Ethical Companies. In 2021, Fortune included Aflac Incorporated on its list of World's Most Admired Companies for the 20th time, and Bloomberg added Aflac Incorporated to its Gender-Equality Index, which tracks the financial performance of public companies committed to supporting gender equality through policy development, representation and transparency, for the second consecutive year. To find out how to get help with expenses health insurance doesn't cover, get to know us at aflac.com.

Forward Looking Statements

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sebela Pharmaceuticals under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the development, launch, introduction and commercial potential of FirstSight™; growth and opportunity, including peak sales and the potential demand for FirstSight™, as well as its potential impact on applicable markets; market size; substantial competition; our ability to continue as a growing concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third-party payer reimbursement; dependence upon third parties; our financial performance and results, including the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; and risks related to failure to obtain FDA and/or CMS clearances or approvals and noncompliance with FDA regulations. As with any diagnostic under development, there are significant risks in the development, regulatory approval and

commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Sebela Pharmaceuticals does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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ⁱ Friedland, S., et al. (2021). Development and clinical validation of a blood test for early detection of colorectal adenomas and cancer. *Journal of Clinical Oncology*, 39(3), 50-50. DOI: 10.1200/JCO.2021.39.3_suppl.50

ⁱⁱ Friedland, S., et al. (2020). A sensitive and quantitative multimodal blood test for the detection of colorectal adenomas and cancer: Correlation with size and number of polyps. *Journal of Clinical Oncology*, 38(15). 1555-1555. DOI: 10.1200/JCO.2020.38.15_suppl.1555

ⁱⁱⁱ Tsai, WS., et al. (2019). Novel Circulating Tumor Cell Assay for Detection of Colorectal Adenomas and Cancer. *Clinical and Translational Gastroenterology*, 10(10). DOI: [10.14309/ctg.0000000000000088](https://doi.org/10.14309/ctg.0000000000000088)

^{iv} Tsai, WS., et al. (2019). Circulating tumor cell count from a blood sample for colorectal cancer (CRC) prevention: A 627-patient prospective study. *Journal of Clinical Oncology*, 37(4). 485-485. DOI: 10.1200/JCO.2019.37.4_suppl.485

^v Tsai, WS., et al. (2018). Prospective clinical study of circulating tumor cells for colorectal cancer screening. *Journal of Clinical Oncology*, 36(4). 556-556. DOI: 10.1200/JCO.2018.36.4_suppl.556

^{vi} American Society for Gastrointestinal Endoscopy. (n.d.). *What is Colorectal Cancer?* asge.org/screenforcoloncancer/what-is-colorectal-cancer

^{vii} Joseph DA, King JB, Dowling NF, Thomas CC, Richardson LC. *Vital Signs: Colorectal Cancer Screening Test Use — United States, 2018*. MMWR Morb Mortal Wkly Rep 2020;69:253–259. DOI: <http://dx.doi.org/10.15585/mmwr.mm6910a1>.

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