CALCIVIS receives Approvable Letter for its unique CALCIVIS® Imaging System from US FDA

CALCIVIS System, developed to enable and drive the adoption of preventive dentistry – enables real-time visualisation of active tooth decay

Edinburgh, March 5th 2020 - CALCIVIS, a medical devices company focused on modernising the management of tooth decay and enabling preventive dentistry, announces receipt of an Approvable Letter for the Premarket Approval (PMA) of its CALCIVIS® Imaging System from the US Food and Drug Administration (FDA). CALCIVIS intends to introduce this novel product in the US in 2021 with the aim of creating a new preventive dentistry market segment in the US, projected to be worth up to $0.5 billion per year. The CALCIVIS® Imaging System PMA approval by FDA is subject to customary preapproval facilities inspections.

The CALCIVIS Imaging System is a sophisticated medical device and biologic combination that highlights the presence of free calcium ions released during tooth demineralisation. Its use enables dentists, for the first time, to differentiate in real-time between active and inactive lesions on tooth surfaces. The CALCIVIS Imaging System provides visual evidence of active decay at an early stage.

This new approach is expected to change care planning and intervention for patients, leading to better preservation of their original teeth and improved oral health. The CALCIVIS Imaging System achieves this by enabling dentists to establish the need for preventive treatments such as remineralisation agents and sealants by differentiating active caries lesions from both sound enamel and inactive caries lesions.

The Approvable Letter is based around positive data from the pivotal clinical study, which evaluated the CALCIVIS Imaging System in the assessment of active dental demineralisation compared with the current best standard of care. Results showed a highly significant level of agreement between the clinical assessment of the original dentist and the independent dentist's assessment using the CALCIVIS Imaging System for teeth with active lesions (90.7%; $p<0.0001$) and sound (healthy) teeth (97.8%; $p<0.0001$).

CALCIVIS is working towards a US test launch of the CALCIVIS Imaging System in 2021 through its own commercial organisation in Massachusetts, based out of its US HQ in Boston. A full US national rollout of the System is planned to begin in 2022.

Adam Christie, CEO of CALCIVIS, said: "The receipt of an Approvable Letter from FDA is a very important step as we prepare to launch the Calcivis Imaging System in the world's largest dentistry market. We are confident that CALCIVIS can help to establish a new standard of preventive care in US dentistry. The System enables clinicians to implement preventive strategies for caries management early in the caries process when it is still reversible, before cavities form. We also know that CALCIVIS images help patients to understand their condition and to value preventive interventions by their dentist. Our technology helps dentists and patients to collaborate in promoting better oral health."

Dr Sarah Hardy, Chief Investment Officer at Archangels, said: "From the very beginning we have believed in the potential of CALCIVIS to make this step change in preventive dentistry. Today's announcement is a major corporate milestone in achieving this goal, which will ultimately allow the CALCIVIS Imaging System to help dentists in the US to better preserve their patients' teeth. CALCIVIS is now planning the US launch of this novel system via its own commercial organisation in the world's largest dentistry market and we are confident of success that will bring significant return to shareholders."

Kerry Sharp, Director, Scottish Investment Bank, said: "The Approvable Letter from FDA for the CALCIVIS Imaging System is a massive achievement for CALCIVIS and rewards the faith in Adam and his team over many years. Given the clear benefits the System delivers to both dentists and patients, I am confident that the CALCIVIS commercial team will drive significant uptake of this novel technology once launched, heralding a new era in preventive dentistry in the US."

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About CALCIVIS www.calcivis.com

CALCIVIS is an innovative medical devices company focused on modernising the management of dental caries or 'tooth decay'. CALCIVIS brings together novel biotechnology approaches and world-class device development expertise and is at the forefront of applying biotechnology to make preventive dentistry a reality.

The CALCIVIS Imaging System, which has received an Approvable Letter from the US FDA and is currently approved in Europe, enables dentists to capture and store images of tooth surfaces with labelled free calcium ions, consistent with demineralisation in active caries. These images therefore provide important information for the implementation of preventive strategies for caries management. This new approach is expected to change care planning and intervention for patients, leading to better preservation of their original teeth and improved oral health.

CALCIVIS began operations in 2012 and is based in Edinburgh, Scotland. The Company has been funded by Archangel Investors Limited and the Scottish Investment Bank (the investment arm of Scottish Enterprise) and Julz (a US-based healthcare fund). The Company has raised equity and grant funding totalling over £14m.

CALCIVIS has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 666440 and Innovate UK's Biomedical Catalyst.

About FDA Premarket Approval (PMA)

Premarket approval (PMA) is the FDA regulatory route for approving innovative Class III medical devices.

It is the most stringent type of device marketing application required by FDA, and PMA approval must be received prior to marketing the device. Approvals are based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s), and typically requires human clinical trial data along with laboratory testing.

Most medical devices (Class I and II) are approved via the 510k process, which covers evolutionary products and consists in proving that the medical device is substantially equivalent to a device that has already been approved for marketing by the FDA.

About Archangels www.archangelsonline.com

Archangels is a prominent business angel syndicate which has been at the forefront of early stage investing in Scotland for more than two decades. Its members invest in, and mentor, promising start-up and early stage companies from Scotland's vibrant technology and life sciences sectors. Originally formed in 1992 and based in Edinburgh, the syndicate now comprises over 130 investor members and leads investment of around £15m per year in early stage Scottish companies, including leverage from partners, the largest being the Scottish Investment Bank. Archangels is interested in Scottish technology companies, which are looking for initial funding of £50,000 to £2m. In addition, Archangels is keen to welcome new investors to its syndicate.

About the Scottish Investment Bank

The Scottish Investment Bank (SIB) is the investment arm of Scotland's national economic development agency, Scottish Enterprise, operating Scotland-wide in partnership with Highlands and Islands Enterprise (HIE). SIB's activities support Scotland's SME funding market to ensure businesses with growth and export potential have adequate access to growth capital and loan funding. We help ambitious Scottish companies get the right levels of funding from the right sources at the right time through building relationships with both domestic and international investors.

SIB manages a suite of co-investment funds including the Scottish Co-investment Fund, the Scottish Venture Fund and the Energy Investment Fund on behalf of the Scottish Government. SIB is an investor in Epidarex Capital's Life Sciences Fund. SIB also administer the Scottish Loan Scheme, with funding secured from the Scottish Government's Scottish Growth Scheme.

SIB also provides funding into LendingCrowd, Scotland's marketplace lender providing loans to SMEs, and Maven's UK Regional Buy Out Fund (MBO) that offers financial support for management buyouts and helps existing management teams acquire their businesses from their owners so they can continue to flourish. SIB's team of financial readiness specialists help companies to prepare for new investment and access appropriate finance.

About Julz www.julzco.com/

Julz Co, LLC is an investment management company focused on the health care industry with an emphasis on therapeutics, diagnostics and digital healthcare. The company has offices in Chapel Hill, North Carolina, USA and Suzhou, China.