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Intelligent Ultrasound Group plc

("Intelligent Ultrasound" or the "Company")

FDA filing submitted for second ScanNav AI software

Intelligent Ultrasound (AIM: MED), the artificial intelligence (AI) based ultrasound software and simulation company, announces that it has submitted its De Novo filing to the US Food & Drug Administration ('FDA') for its ScanNav AnatomyGuide Peripheral Nerve Block (PNB) artificial intelligence-based software.

Following on from the CE regulatory submission in July this year, and subject to CE and FDA approval, the Company is aiming for initial revenues in the second half of 2021.

The ScanNav AnatomyGuide PNB AI software will, automatically and in real-time, identify and highlight structures such as nerves and arteries on the live ultrasound scan image that are important to be identified during PNB needling procedures.

ScanNav AnatomyGuide PNB Trainer, a classroom-based version of the product, that does not require regulatory approval and aims to provide pre-clinical teaching to clinicians, is expected to be available for sale to hospital training departments during Q1 2021.

Both products will initially be sold through the Group's existing direct sales channels in the UK and North American markets.

Nicholas Sleep, CTO of Intelligent Ultrasound, said:

"This is an important milestone in the process of bringing our ScanNav AnatomyGuide AI software to market. Although we continue to discuss with manufacturers the option of integrating our software into their future ultrasound machines, the FDA and CE submissions are a key step in enabling us to bring our own ultrasound AI products to market in 2021."

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About Intelligent Ultrasound Group

Intelligent Ultrasound (AIM: MED) develops artificial intelligence-based clinical image analysis software tools for the diagnostic medical ultrasound market and hi-fidelity virtual reality simulators for the ultrasound training market.

Based in Cardiff in the UK and Atlanta in the US, the Group operates two divisions:

Clinical AI Division

Focusses on developing deep learning-based algorithms to make ultrasound machines smarter and more accessible. Products in development include *ScanNav* which uses machine-learning based algorithms to automatically identify and grade ultrasound images to provide scan assessment and audit of protocol-based ultrasound scanning; and *ScanNav AnatomyGuide*, which aims to simplify ultrasound-guided needling by providing the user with realtime AI-based anatomy highlighting software for a range of medical procedures.

Simulation Division

Focusses on hi-fidelity ultrasound education and training through simulation. Its three main products are the *ScanTrainer* OBGYN training simulator, the *HeartWorks* echocardiography training simulator and the *BodyWorks Eve* Point of Care and Emergency Medicine training simulator. To date over 900 simulators have been sold to over 500 medical institutions around the world.

www.intelligentultrasound.com

Al products in development may require US FDA or other regulatory approval, as such this material should be considered informational only and does not constitute an offer to sell or infer claims or benefits.