

TruSpine Technologies plc
(**"TruSpine"** or the **"Company"**)

FDA Update

TruSpine Technologies plc, (AQSE: TSP) the medical device company focused on the development of its pioneering "screwless," spinal (vertebral) stabilisation systems, provides an update in relation to its FDA submissions.

Further to the announcement of 28 April 2022, the Company is in a position to file its 510k FDA submission, however it is awaiting the FDA's response to the Company's request for a Breakthrough Technology Designation ("BTD").

Once a decision has been communicated to the Company, the Company will file either a BTD 510k application or a standard 510K application following receipt of FDA response. The Directors anticipate that the FDA response and subsequent submission is-are expected by the end of July 2022 in the coming weeks and an announcement will be made in due course.

If "Breakthrough Device Technology" designation is conferred it should bring significant long-term benefits in the commercialisation of Cervi-LOK™, including higher margin as a result of preferred insurance coding and hospital reimbursement. The "Breakthrough Device Technology" designation would also reduce the time to an FDA 510k application clearance from 90 days to 60 days if granted.

Ian Roberts, CEO of TruSpine commented: 

This announcement contains inside information for the purposes of the UK Market Abuse Regulation and the Directors of the Company are responsible for the release of this announcement.

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Caution regarding forward looking statements

Certain statements in this announcement, are, or may be deemed to be, forward looking statements. Forward looking statements are identified by their use of terms and phrases such as "believe", "could", "should" "envisage", "estimate", "intend", "may", "plan", "potentially", "expect", "will" or the negative of those, variations or comparable expressions, including references to assumptions. These forward-looking statements are not based on

historical facts but rather on the Directors' current expectations and assumptions regarding the Company's future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. Such forward looking statements reflect the Directors' current beliefs and assumptions and are based on information currently available to the Directors.