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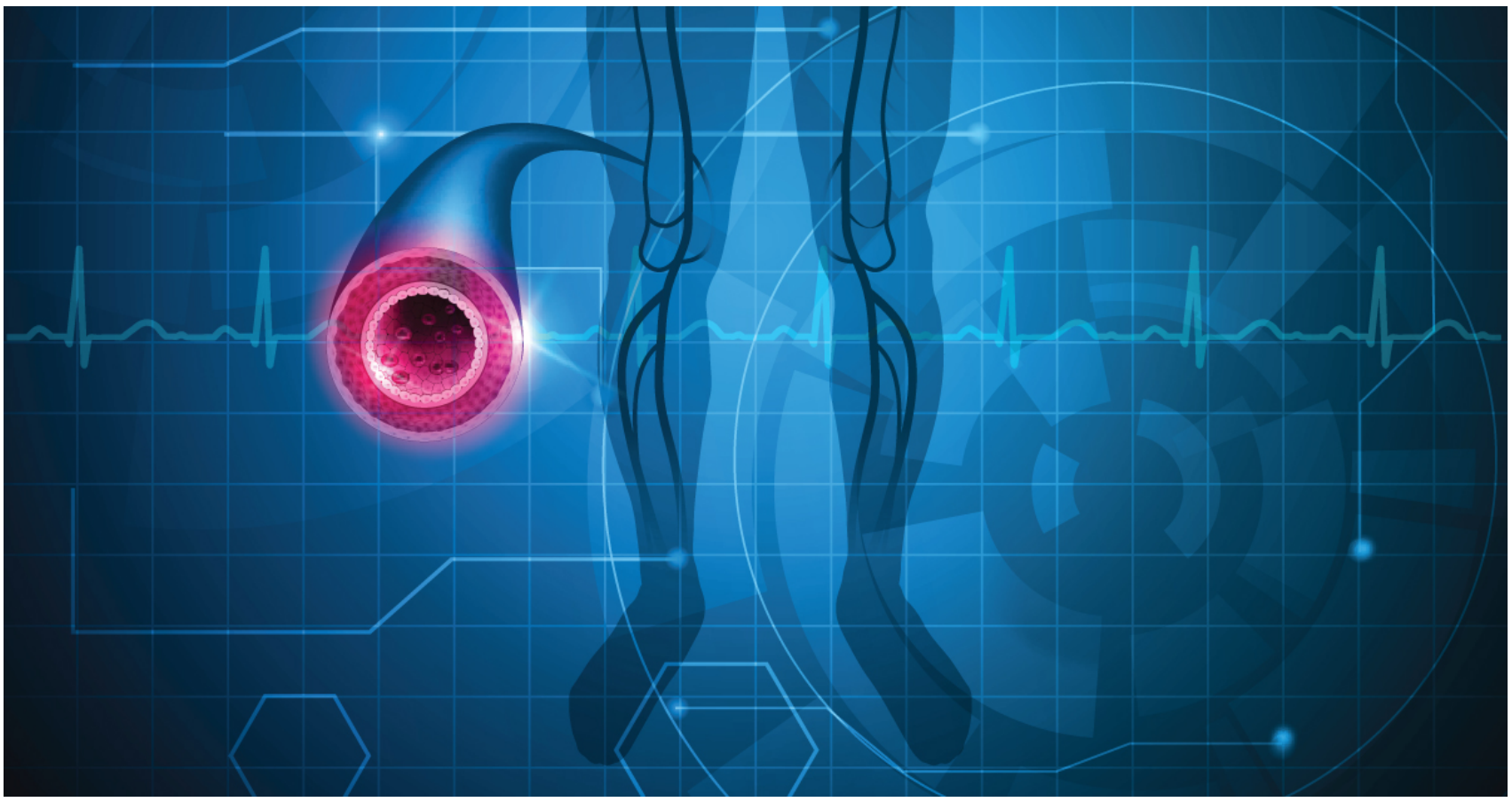
Bioprosthetic valve for chronic venous insufficiency nets breakthrough device status

Hancock Jaffe Laboratories announced that the FDA has granted breakthrough device designation status to its bioprosthetic valve for the treatment of chronic venous insufficiency.

Breakthrough devices receive priority FDA review; the designation allows early interaction with FDA personnel to expedite the review and approval process.



Source: Adobe Stock

According to a company press release, the new valve (VenoValve) is a porcine-based valve intended to be surgically implanted in the deep venous system of the leg to treat reflux associated with chronic venous insufficiency.

According to Cleveland Clinic, chronic venous insufficiency occurs when the venous wall and/or valves in the leg are not working effectively and make it difficult for blood to return to the heart from the legs.

According to the company release, data from the first-in-human study of the new valve, presented in December of 2020, indicated an average reflux improvement of 54%, average improvement in disease manifestations of 56% and average improvement in pain of 76% at 1 year after valve implantation compared with pre-implantation measurement. There were no material adverse events at 30 days following valve implantation, according to the release.

"We are very pleased to have the opportunity to work with the FDA on an expedited basis as we try to bring relief to the millions of patients who suffer from deep venous CVI and who currently have no effective treatment options," **Robert Berman**, CEO of Hancock Jaffe Laboratories, said in the release. "The VenoValve significantly improved the lives of the patients in our first-in-human study, and we hope to replicate that success in our SAVVE U.S. clinical trial."