Humacyte Statement on New York Times Article

DURHAM, N.C., March 27, 2025 – Dr. Laura Niklason, President and CEO of Humacyte, Inc. (Nasdaq: HUMA), released the following statement today:

"Earlier this week, *The New York Times* published a story questioning the Food and Drug Administration's (FDA's) decision to approve Symvess™ for commercial sales. Until now, I have refrained from commenting because our company was in a quiet period while finalizing a new round of financing to support our important work. With the close of today's market, I now have an opportunity to set the record straight, and I will do so here."

"First, the FDA conducted a rigorous review of our Biologics License Application (BLA) of Symvess, which took longer than one year. After a consultant on the file, Dr. Robert E. Lee, raised his concerns during the review, the agency considered convening an Advisory Committee of outside experts, which they were entitled to do. We did not object to this. The FDA decided against convening an Advisory Committee, and instead engaged in extensive internal consultation, and also asked three experienced vascular surgeons outside the FDA to offer their perspectives on Symvess for treating traumatic injuries."

"It took time to complete the internal discussions at the FDA regarding Dr. Lee's objections, and to compile responses from outside experts. Although our original PDUFA date was August 10, 2024, the FDA took an additional 19 weeks to complete its review of the risks and benefits of Symvess. After taking all views into account, the FDA agreed that our product was safe and effective for use in repair of vascular trauma of the extremities in situations where there is an urgent need for revascularization and where autologous vein grafting is not feasible. The agency issued its approval of Symvess on December 19, 2024."

"The FDA's review process was conservative and time consuming, but that's how it should work. We all want federal agencies to take their responsibilities seriously, and I appreciate that the FDA took the time it needed to evaluate our product. Furthermore, as part of the FDA's review of Symvess, we are committed to conducting a post-approval study to continue to assess the rate and severity of adverse events in trauma patients treated with Symvess. We are developing this study right now, and we remain confident that it will confirm the safety and effectiveness of Symvess that we have already witnessed in two previous trials, and that led to our FDA approval in the first place."

"What is deeply troubling is that the *Times* relied on a single source for the majority of its reporting in this story: Dr. Lee, who was not part of the formal review team for Symvess at the FDA. Lee has since left the government and has co-founded a consulting firm focused on helping companies obtain medical device approvals. Despite reporting that he left the FDA in protest over the agency's decision, Dr. Lee actually resigned in late September, long before the FDA made the decision to approve Symvess. His own LinkedIn biography mentions that he retired 'after an enjoyable and rewarding decade at FDA.'"

"Other substance of the *New York Times* coverage also leaves much to be desired. The reader is told that ruptures of synthetic grafts – made from highly fluorinated plastic materials such as Teflon – are 'unheard-of.' Any trauma or vascular surgeon who has treated a ruptured Gore-Tex graft will tell you this is untrue. Indeed, in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which contains reports of some medical device failures, more than one quarter of synthetic graft failures are associated with graft rupture and/or patient death. Had the reporter asserted that synthetic grafts do not fail when she spoke with me, I would have disputed her characterization in the strongest terms."

"Likewise, the reader is told that 'shrapnel wounds are not the devastating wounds typically seen on the battlefield.' I've seen the injuries that Ukrainian surgeons repaired using Symvess on the frontlines of that conflict. Shrapnel injuries are among the most debilitating and difficult for even the most experienced surgeons to repair. Pictures of these devastating injuries are available to anyone taking the time to review the multiple medical conference presentations describing Humacyte's humanitarian effort in Ukraine with Symvess. Had the reporter asked me to comment on this, I would have told her how wrong she was. As mentioned in our approved label for Symvess, the Ukrainian patients in our study with wartime injuries treated with Symvess, all retained their treated limbs at Day 30, with zero infections."

"There are other portions of the story that I take exception with – too numerous to detail here – but I want to reiterate that Humacyte takes safety concerns very seriously. We believe strongly in both the safety and effectiveness of our product. In our civilian trauma trial of Symvess, which treated severely injured patients suffering gunshot wounds, crush injuries, and stab wounds, the resulting limb salvage and other outcomes were excellent. An independent safety review committee concluded that any instances of amputation or patient death were due to the underlying injuries and complications, and not due to Symvess."

"I started this company 20 years ago because I wanted surgeons and patients to have a better option for treating vascular injuries and disease. Over the past 12 years, Humacyte's engineered vessels have treated more than 600 patients in 9 separate clinical studies. Our studies have never been halted for any safety concern. As the FDA noted last December, Symvess is an innovative product that offers 'potentially life-saving benefits for patients with severe injuries.' We look forward to the important work ahead to make that goal a reality for trauma patients here in the United States."