MonarchBio Continues to Build Substantial Thin-Film Nitinol Patent Portfolio

Announces Four Recent Notices of Allowance of U.S. Patent Applications

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Monarch Biosciences
Jan 12, 2021, 08:51 ET

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LOS ANGELES, Jan. 12, 2021 /PRNewswire/ -- Monarch Biosciences, Inc. (MonarchBio), a California-based life sciences company, announced today that it has recently received Notices of Allowance from the U.S. Patent and Trademark Office (USPTO) for the following U.S. patent applications:

- No. 16/298,758 entitled "Three-Dimensional Thin-Film Nitinol Devices" (U.S. Patent 10,864,096)
- No. 16/010,341 entitled "Intrasaccular Thin-film Flow Diverters and Related Methods"
- No. 15/605,754 entitled "Thin-Film Cuff for Endothelialization of Endovascular Grafts"
- No. 16/048,136 entitled "Thin-Film Micromesh and Related Methods"

Haynes and Boone LLP represented MonarchBio in the successful prosecution of these patent applications and other related applications.

The claims of the patent applications cover the manufacturing of three-dimensional thin-film nitinol (TFN) constructs and include TFN-based intrasaccular flow diverters, cuffs for endovascular grafts and thin-film micromesh devices, which may be fabricated via sputter deposition on a micropatterned silicon wafer. Nitinol is a super-elastic nickel and titanium alloy with unique properties that allow deformation and subsequent full recovery of the original shape upon exposure to body heat.

"MonarchBio has amassed a substantial intellectual property portfolio comprised of patents and trade secrets covering both fabrication of its advanced TFN biomaterial and novel devices that leverage TFN's unique physical and biological properties," said Colin Kealey, M.D., Chief Medical Officer of MonarchBio, adding, "Our current efforts are focused on TFN-based neurovascular devices and the use of TFN for localized cell therapy delivery."

"We are very excited by the recent patent issuances by the U.S. Patent and Trademark Office. These awards enhance MonarchBio's intellectual property protections surrounding our lead devices, including our *Titan Flow Diverter*. The unique attributes of MonarchBio's intellectual property, including our 3-D fabrication capabilities, have allowed us to optimize the flow diverter and progress from a development-stage company to transitioning to a clinical-stage company," said Vikas Gupta, MonarchBio's Vice President of Engineering, adding, "Recent pre-clinical results of MonarchBio's flow diverter in both animals and a human simulator at Mayo have been robust. These results are the culmination of over ten years of intense engineering and assembly advances and prepare us for the next step – seeking regulatory approval to proceed with the first-in-human clinical trial."

"MonarchBio's patent portfolio and trade secrets, coupled with our first mover advantage, provide us with a sustainable competitive advantage. MonarchBio's TFN is a nanotechnology platform with the potential for treating a wide spectrum of indications," said Leon Ekchian, Ph.D., MonarchBio's President and CEO. "We are partnering with established medical device and pharmaceutical companies to commercialize TFN-based medical products for applications including endovascular therapy, cell therapy, drug delivery and wound healing," added Ekchian.

CAUTION: In the United States, the *Titan Flow Diverter* is an investigational device and is limited by United States Federal law to investigational use.

About MonarchBio

MonarchBio is a Los Angeles-based life sciences company focused on development and commercialization of its unique Thin Film Nitinol (TFN) biomaterial platform for use in advanced medical device, biotechnology, and regenerative medicine products. TFN is fabricated in-house using techniques adapted from the electronics industry. An ultra-pure film of nitinol, 1-20 micrometers thick (for comparison, the average human hair is approximately 50 micrometers thick), is deposited on a silicon wafer with a specially designed micropatterned surface. When the film is removed from the wafer, it maintains the shape or pattern on the wafer surface. MonarchBio has twenty-one issued or allowed U.S. patents, in addition to having exclusively licensed a portfolio of patents from UCLA and the Fred Hutchinson Cancer Research Center related to various applications of TFN technology. MonarchBio was formed in 2011 and in 2012, MonarchBio acquired a portfolio of patents and related trade secrets covering the fabrication of Thin-Film Nitinol (TFN) from TiNi Alloy Company.

MonarchBio's lead product under development – the ***Titan Flow Diverter™*** - is a TFN-covered stent, which offers potentially superior and more rapid occlusion of cerebral aneurysms compared with current leading neurovascular products in the market. The unique properties of TFN allow for the fabrication of flow diverters that can be compressed and inserted through very small catheters into blood vessels and positioned over the neck of the aneurysm. The *Titan Flow Diverter* uses an omni-directional thin film mesh that covers a custom neurovascular support stent. Once deployed, the *Titan Flow Diverter* serves a dual purpose: (1) it restricts blood flow into the aneurysm, which in turn causes the aneurysm to stagnate, and (2) it acts as a scaffold for rapid re-endothelization of the vessel wall. MonarchBio has completed preclinical animal and recent human simulator testing at Mayo Clinic's campus in Rochester, Minnesota.

Approximately 30,000 cerebral aneurysms rupture annually in the United States and the market for flow diverting stents is approximately $300 million annually.

The second product in its pipeline, the ***Engineered Lymph Node™ (ELN)***, is a TFN-based device for local delivery of cell therapies treating solid tumors. The *ELN* provides a scaffold for delivering ultra-high densities of anti-cancer lymphocytes, including CAR-T, TCR and NK cells, directly to the tumor. Once in place, the ELN provides an immunostimulatory microenvironment that fosters rapid expansion of the anti-cancer lymphocytes and a robust anti-tumor effect in multiple preclinical models. Work at Fred Hutchinson Cancer Research Center (Seattle, Washington) in a mouse model of metastatic ovarian cancer using ROR1-directed CAR-T cells delivered on the ELN showed a long-term survival of 70% as compared to 100% mortality after 65 days in mice receiving intravenous or intratumoral injections of the CAR-T cells ($p < 0.001$).

For more information, please visit www.monarch-bio.com.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements, including but not limited to, research and development outcomes, efficacy, adverse reactions, market and product potential, product availability and other statements regarding our *Titan Flow Diverter™*. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Risks and uncertainties include, among other things, general industry and medical device market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and regulatory processes; challenges related to new product marketing, such as the unpredictability of market acceptance for new medical device products; inconsistency of treatment results among patients; potential difficulties in manufacturing a new product; general economic conditions; and governmental laws and regulations affecting domestic and foreign operations.

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