

Profile

DanDrit Biotech

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How and when did your company start, and where are you located?

Dandrit Biotech was founded in Denmark in 2001. We are a US company (375 Park Ave, Suite 2607, New York, NY, 10152, USA) with a fully-owned Danish subsidiary (Symbion Science Park, Fruebjergvej 3, 2100 København Ø, Denmark). We are listed on OTCQB under the symbol DDRT.

How many employees do you have, and how do you find and attract them?

Dandrit Biotech is organized under a virtual model with 4 employees. The manufacturing is outsourced to Cellin Technologies in Estonia. The management of our Phase III clinical trial in Italy is outsourced to GISCAD (Italian Group for the Study of Gastrointestinal Carcinoma).

What are the main focus and platform technology(ies) of your company?

Dandrit Biotech's lead compound, MelCancerVac (MCV) is a dendritic cell vaccine. Our clinical development program focuses on VIVA, a Phase III adjuvant trial of MCV in patients with no evidence of disease (NED) stage IV colorectal cancer (CRC). The primary aim of the VIVA clinical trial is to evaluate the efficacy of MCV in stage IV CRC patients rendered disease-free after completion of standard treatment according to local practices. Prof. Alberto Sobrero will be the principal investigator of this randomized multi-center study.

Can you provide a short overview of your product pipeline?

- MCV:
 - MCV is in Phase III clinical trial in CRC (multi-center Italy and USA)
 - We are discussing with Chinese FDA to initiate similar Phase III CRC in China
 - MCV also completed a Phase II in Non-Small Cell Lung Cancer (NSCLC). We are planning a second trial in NSCLC in adjuvant setting in patients with stage IIIa NSCLC (EU location to be determined)
 - We plan to initiate an esophageal cancer trial in the USA (scheduling Pre-IND meeting with FDA)
- Preclinical:
 - Tolerogenic dendritic cell vaccine
 - 100% off-the-shelf cancer vaccine

Who is your competition, and what advantage(s) do your products / technology offer?

Bavarian Nordic with PanVax (Phase II). PanVax is a viral vector vaccine. Our price is also very competitive but Bavarian Nordic did not communicate on the future price of its cancer vaccines (Prostvac and Panvac).

What were the "highlights" in your recent product development?

Initiate the Phase III trial in collaboration with GISCAD and Prof. Sobrero (as Principal investigator).

What have been the most critical problems in developing products in your field, and how can your company's technology help overcome these problems?

Pricing and logistics are two key challenges for cell therapy. We demonstrate that we are ready for commercialization through a large-scale compassionate Use Program run in collaboration with a Dutch company myTomorrows (see mytomorrows.com).

What is your company's value proposition?

We want to be the first to offer a safe adjuvant therapy to prevent relapses of metastatic CRC.

What business development strategy do you pursue?

Dandrit Biotech is built on a virtual model to facilitate a trade-sale or a collaboration with an established pharmaceutical partners. Several contacts have been initiated and we aim to partner the development of MCV at interim results of our Phase III trial.

How does your company attract partners?

We have collaborated with pharma partner in the elaboration of our Phase III trial. Under CDA, several pharmaceutical companies were offered the opportunity to submit their input in the design of the trial. We keep close contact with potential pharmaceutical partners at different conferences.

Who are your most important partners?

At this stage of clinical trial we are not looking at pharma partners. Our key partnerships are with Cellin Technologies (manufacturing center in Europe), Riyadh Pharma (manufacturing and commercial development in the Middle East) and with myTomorrows (Compassionate Use Program).

How do you balance performing work in-house vs out-sourcing?

At equal quality and cost we favor outsourcing in order to decrease fixed costs and increase the facility to be acquired. Quality-control is one exception to this rule.

What are your product development goals for the next 3 years?

Partnership agreement for clinical development of MCV or a trade-sale with a large pharmaceutical company or an oncology specialty pharma.

To know more, visit:
www.dandrit.com