ChemioCare Developing New Lenalidomide Skin Patch

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Inês Martins, PhD

April 26, 2019

Aiming to improve lenalidomide's safety and efficacy, ChemioCare is setting up to develop a new treatment formulation delivered through a skin patch, maintaining an optimal blood level of the medicine for prolonged periods of time.

The new formulation uses the company's permeation-enhanced transdermal technology (PETT), which "works like a continuous injection of drug into the bloodstream that can be precisely delivered to provide the right amount of drug to work without providing too much drug, which can cause toxicity," Jamie Oliver, ChemioCare's chief marketing officer, said in a press release.

Lenalidomide — marketed as Revlimid by Celgene — is the standard of care for multiple myeloma patients, and is approved for some patients with myelodysplastic syndrome and mantle cell lymphoma.

The treatment is an immunomodulatory agent that stimulates the immune system to fight cancer and blocks the formation of new blood vessels around the tumor, preventing tumor growth through these two mechanisms.

But despite being delivered orally, which is more convenient for patients than intravenous infusions, Revlimid has significant dose-dependent side effects, such as low numbers of white blood cells, which ultimately reduces its tolerance and leads to dose reductions or treatment discontinuation.

The biggest problem with Revlimid, researchers say, are its fluctuating levels. The agent reaches its highest concentration after the pill is taken, but levels then drop continuously until the next dose. While the highest dose may cause treatment toxicity, the lowest levels

may lead to treatment failure.

“Oral medications just are not able to precisely maintain the optimal blood levels over the dosing interval,” Oliver said.

Thus, a possible solution is to keep lenalidomide at its optimal levels at all times, which might be achieved via a device that continuously releases the agent into circulation. ChemioCare is hoping its lenalidomide PETT is the answer.

Because a lenalidomide formulation is already approved, this skin patch leverages the 505(b)2 regulatory path, allowing it to enter Phase 3 trials directly without the need for prior safety, dose-finding studies.

“We are delighted to launch the first program out of the PETT prioritization project, which has the potential to transform the multiple myeloma treatment paradigm,” said Pedro Lichtinger, chairman and CEO of ChemioCare.

Also, lenalidomide’s protection on its composition of matter is set to expire by year’s end, and companies might begin marketing generic, cheaper versions of the medicine as early as 2022.