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Proteolix seeks fast OK on drug

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Proteolix Inc. plans to seek accelerated FDA approval for a multiple myeloma drug now in a mid-stage trial.

Carfilzomib would be one of the early entrants in a class of drugs called proteasome inhibitors. Proteasomes control the turnover of proteins in cells, and researchers found that cancer cells are especially sensitive to proteasomes being blocked.

The Food and Drug Administration in 2003 approved Millennium Pharmaceuticals' Velcade as the first proteasome inhibitor drug.

Accelerated FDA approval for Proteolix's carfilzomib would allow the privately held, South San Francisco company to offer its drug to multiple myeloma patients who have failed every other treatment — even while the company continues to gather more data in a latter-stage study.

Proteolix President and CEO Chip Scarlett said the company plans to file for accelerated approval late next year.

“The study we have in process right now, we still call it a Phase II, but hopefully it will form the basis for the main pivotal study for accelerated approval,” said Scarlett, who joined the company in February.

Proteolix also expects to put an oral form of carfilzomib into the clinic early next year, said Susan Molineaux, the company's founder and chief scientific officer. Another drug, an immunoproteasome inhibitor that could target problems like rheumatoid arthritis, also is planned for the clinic next year.

None of the three drugs have a partner, but Proteolix is starting to look at its options, Scarlett said.

Proteolix, with 75 employees, was founded in 2003. It has won \$142 million in venture financing, including \$79 million late last summer.

As it moves forward, Proteolix is relying on strong data, including results from 46 patients presented last month at the American Society for Clinical Oncology meeting. The full trial, which is still enrolling, will include more than 200 patients.

“These are patients who don’t have a lot of other options right now,” said Dr. Susan Kelley, chief medical officer of the Multiple Myeloma Research Foundation and Multiple Myeloma Research Consortium.