

Anthera Pharmaceuticals Inc
Form DEFA14A
April 29, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

SCHEDULE 14A
(RULE 14a-101)

INFORMATION REQUIRED IN
PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities
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Check the appropriate box:

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ANTHERA PHARMACEUTICALS, INC.
(Name of Registrant as Specified in its Charter)

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Dear Fellow Shareholders,

As we build momentum towards our goal of helping patients in need, the importance of our work becomes more obvious. Anthera entered the past year with much excitement and ambition around the initiation of multiple clinical studies focused on a new approach for helping patients with severe autoimmune diseases. Over the years we have made tremendous progress in our understanding of how blisibimod may best help patients, and now we eagerly sit on the cusp of realizing the potential of our efforts.

The CHABLIS Studies in Patients with Severe Manifestations of Lupus

Our first insights into blisibimod's potential were discovered after the completion of the PEARL-SC clinical study in 2012. This clinical study was instrumental in identifying the population of patients with lupus most likely to derive the greatest benefit from blisibimod – who also happened to be the patients most in need - and provided insight into the optimal design of our Phase 3 CHABLIS-SC1 clinical trial. PEARL-SC's companion Open-Label Extension (OLE) study, for which dosing was completed in July 2013, reaffirmed our confidence that blisibimod may be a highly effective treatment option for severely ill patients with lupus compared to the currently available therapies. Throughout 2013, we presented the PEARL-SC and OLE studies at several conferences including the 10th International Congress on SLE (Buenos Aires, Argentina), the European League Against Rheumatism (EULAR Madrid, Spain), and the American College of Rheumatology Annual Meeting (ACR San Diego, California). The complete results of this study will be published this year in the peer-reviewed scientific journal, Annals of Rheumatic Disease. We are thankful for Dr. Richard Furie and the entire PEARL-SC study team for the efforts to advance our scientific understanding of lupus and the role blisibimod may play in the future to treat this terrible disease.

Based on observations from those studies, we initiated CHABLIS-SC1 early in 2013, the first of two pivotal Phase 3 registration studies in lupus. Over the course of the year, we gained significant traction in enrollment, and so far have achieved a rate of enrollment well beyond our planned projection of 100 patients. Of course we are encouraged that simplified patient identification –patients with severe disease activity who are not achieving full response with steroids - may be a sign of the future commercial potential of blisibimod. An interim efficacy analysis of the first group of patients, intended to confirm the clinical and scientific assumptions of the CHABLIS-SC1 study, is slated for later this year.

We submitted the second pivotal study for lupus, CHABLIS-SC2, to the US Food and Drug Administration in the first quarter of 2014 and will begin deploying this protocol globally later this year. When initiated, this study will enroll patients with clinical diagnosis of lupus with or without glomerulonephritis – a common kidney disorder often present in more severe cases of lupus. In fact, many of these intended patients may have had a previous diagnosis of lupus nephritis – a serious manifestation of the disease that is a key limitation of currently available therapy.

BRIGHT-SC and the treatment of IgA Nephropathy

The insight we gained from the PEARL-SC and OLE clinical studies in patients with lupus also supports our clinical development activities in patients with Immunoglobulin A Nephropathy, or IgA Nephropathy (IgAN), and we're especially excited about the potential opportunity to offer IgAN patients the first therapy to address the root cause of their disease. Patients with IgAN are diagnosed by the presence of significant proteinuria (a loss of protein in the urine) and subsequent identification of immune complexes in the kidney following a biopsy. These deposits in the kidney promote inflammation and progression towards kidney failure. Data presented throughout 2013, from our PEARL-SC and OLE studies revealed significant improvements in proteinuria in patients treated with blisibimod. These improvements occurred alongside decreases in levels of immunoglobulins, supporting our hypothesis that blisibimod may reduce the production of immune complexes which will help slow or halt the progression of kidney disease in patients with IgAN. Our BRIGHT-SC clinical study has been enrolling patients throughout Asia – where IgAN is most prevalent. While enrollment has been slower than we hoped, to date patients participating in the study have the exact disease characteristics we are hoping to improve - high levels of proteinuria and signs of progressive renal disease.

Concurrent with our pivotal Phase 2/3 BRIGHT-SC clinical trial, we continue to meet with global regulatory agencies, including the Japanese Pharmaceutical and Medical Devices Agency, and the US Food and Drug Administration to clarify the best pathway forward in hopes of bringing a much needed treatment innovation to patients with IgA Nephropathy. We hope to gain further insight into the progress of this study later this year as part of an interim analysis.

Beyond Immunology - A New Approach for Multiple Myeloma

Finally, over the past year we have begun to look for roles for blisibimod beyond immunology. We have recently initiated pre-clinical studies evaluating the potential for blisibimod, in combination with proteasome inhibitors, to treat multiple myeloma - a form of cancer of human plasma cells within the bone marrow that is associated with high mortality. We plan to provide more data on this program throughout 2014.

Advancing blisibimod for patients with severe autoimmune diseases remains our highest priority and we continue to make significant progress both in the clinic and with potential partners who may help accelerate our efforts. I hope that you, our Anthera shareholders, take pride in the continual progress of our company in pursuit of life-changing and life-saving therapies. I thank our employees – and the many people we work with – for their outstanding contribution and support, which undeniably facilitated the delivery of a very transformational 2013. And finally I would like to thank Dr. James Healy who departed our Board of Directors earlier this year. Jim, and his entire organization, have been strong advocates for Anthera over the years and we were fortunate to have their counsel, advice and friendship.

I am excited about the potential for Anthera to emerge with a new therapy that is meaningful to many people. I am hopeful we can help women whose lives have been unfairly altered by a disease we are just now beginning to better understand. I am inspired by a leading Japanese nephrologist who exclaimed to his own government about the need to pay attention to our IgAN study as a way to remove the death sentence for thousands of people with a deadly kidney disease. And now, I wonder if we may have a new hope for those with a deadly form of blood cancer.

We are determined in our efforts to bring blisibimod forward as a promising therapy to improve the lives of patients and remain ever grateful for your support and encouragement.

Chief Executive Officer

April 28, 2014
