Regulatory,
from previous page

structural damage and improve physical function in patients with active psoriatic arthritis. The chimeric monoclonal antibody against tumor necrosis factor (TNF) alpha is approved for psoriasis in the EU, ulcerative colitis (UC) in the U.S. and for ankylosing spondylitis, Crohn's disease, rheumatoid arthritis (RA) and psoriatic arthritis in the EU and the U.S.

Mission Pharmacal Co., San Antonio, Texas
Product: Tindamax tinidazole
Business: Infectious

Mission Pharmacal submitted an sNDA to FDA for Tindamax to treat bacterial vaginosis. The second-generation nitroimidazole is approved in the U.S. to treat trichomoniasis, the intestinal infections giardiasis and intestinal amebiasis and amebic liver abscess.

Neurochem Inc. (TSX:NRM; NRMX), Laval, Quebec
Johnson & Johnson (JNJ), New Brunswick, N.J.
Product: Kiacta eprodisate disodium (NC-503)
Business: Metabolic

NRM received an approvable letter from FDA for Kiacta to treat amyloid A (AA) amyloidosis. FDA requested additional efficacy data and a safety update, which the agency said could require one or more additional clinical trials but also might be provided by significant findings from a complete follow-up of patients in an existing study. An open-label extension of the Phase II/III trial that supported the NDA is ongoing. FDA also asked for further manufacturing and pharmacokinetic data, and said that a QT study should be submitted as part of a Phase IV commitment. NRM said it has begun collecting the necessary follow-up data, which it expects to submit this quarter. The small molecule inhibitor of amyloid fiber formation has Fast Track and Orphan Drug designations for the indication.

Procter & Gamble Co. (PG), Cincinnati, Ohio
Product: Actonel risedronate
Business: Musculoskeletal

FDA approved a label expansion for 35 mg once-weekly of Actonel to treat osteoporosis in men. The antiresorptive pyridinyl bisphosphonate already is approved in 5 mg daily and 35 mg once-weekly formulations to prevent and treat postmenopausal osteoporosis in women. Actonel 5 mg daily also is approved to prevent and treat glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoid treatment (≥7.5 mg/day prednisone or equivalent) for chronic diseases.

SkyePharma plc (LSE:SKP; SKYE), London, U.K.
Novartis AG (NVS; SWX:NOVN), Basel, Switzerland
Product: Foradil Certihaler formoterol fumarate
Business: Inflammation

The label for asthma drug Foradil inhaled formoterol, a long-acting adrenergic receptor beta 2 agonist (LABA), was updated to include a boxed warning that LABA's may increase the risk of asthma-related death. Schering-Plough Corp. (SGP, Kenilworth, N.J.) holds U.S. rights to NVS's Foradil product line. Late last year, FDA warned that LABAs have been associated with an increased risk of severe asthma episodes and asthma-related death *(see BioCentury, Dec. 5, 2005)*.

Xoma Ltd. (XOMA), Berkeley, Calif.
Product: Neuprex opebacan
Business: Infectious

XOMA is reviewing its option to submit a marketing application to the EMEA for Neuprex to treat meningococcemia under Europe's "exceptional circumstances" legislation. The legislation allows for approval in cases where the applicant is unable to provide comprehensive data on the safety and efficacy of a compound under normal conditions of use. Approval under the pathway would likely entail post-approval study commitments. The company said it will complete its assessment in the first quarter of 2007. Neuprex is a recombinant bactericidal/permeability-increasing (BPI) protein.

CLINICAL RESULTS

Avantogen Oncology Inc. (AVTO), Los Angeles, Calif.
Bioaccelerate Holdings Inc. (BACL), New York, N.Y.
RESprotect GmbH, Dresden, Germany
Product: RP101
Business: Cancer
Molecular target: STAT3 mRNA; Apex gene
Description: Inhibits induced chemoresistance and enhances chemosensitivity
Indication: Treat advanced pancreatic cancer
Endpoint: NA
Status: Interim Phase I data
Milestone: Submit IND (4Q06); start Phase II (early 2007)

Interim data from an open-label Phase I trial in 22 patients showed that RP101 plus gemcitabine led to survival rates of 68% and 39% at 6 and 12 months, respectively. The estimated median survival was 9.3 months.

BioDelivery Sciences International Inc. (BDSI), Morrisville, N.C.
Product: BEMA LA
Business: Neurology
Molecular target: Not available
Description: Long-acting analgesic formulated with the BEMA transmucosal delivery system
Indication: Treat moderate to severe pain
Endpoint: Plasma concentration
Status: Phase I data
Milestone: NA

An open-label, crossover Phase I trial in 12 patients showed that plasma concentrations of BEMA LA were well within the levels associated with analgesic activity. Also, the 24-hour plasma concentrations observed support the potential of once-daily dosing.

Boehringer Ingelheim Corp., Ridgefield, Conn.
Product: Tipranavir
Business: Infectious
Molecular target: HIV protease
Description: Non-peptidic protease inhibitor (PI)
Indication: Treat HIV infection
Endpoint: Determine maximum tolerated dose
Status: Phase II data
Milestone: NA

Data from an open-label, international Phase II trial in 115 HIV-infected children showed that tipranavir plus ritonavir (tipranavir/r) combination treatment led to virologic and immunologic improvements at 48 weeks of therapy. Patients received either 290/115 or 375/15 mg/m^2 twice-daily tipranavir/r. For patients taking the lower dose, 39.7% of patients achieved viral loads of <400 copies/mL and 34.5% achieved undetectable viral loads of <50 copies/mL. For the patients receiving the higher dose, 45.6% achieved viral loads of <400 copies/mL and 35.1% achieved undetectable viral loads. Data were presented at the International AIDS meeting in Toronto.

See next page

Clinical Status,
from previous page

Avantogen Oncology Inc. (AVTO), Los Angeles, Calif.
Bioaccelerate Holdings Inc. (BACL), New York, N.Y.
RESprotect GmbH, Dresden, Germany
Product: RP101
Business: Cancer
Molecular target: STAT3 mRNA; Apex gene
Description: Inhibits induced chemoresistance and enhances chemosensitivity
Indication: Treat advanced pancreatic cancer
Endpoint: NA
Status: Phase II start
Milestone: Start Phase II (early 2007)

By early next year, AVTO will begin a Phase II trial comparing 750 mg daily of RP101 plus gemcitabine to gemcitabine plus placebo.

BioMS Medical Corp. (TSX:MS), Edmonton, Alberta
Product: MBP8298
Business: Autoimmune
Molecular target: NA
Description: Synthetic myelin basic protein (MBP) peptide
Indication: Treat secondary progressive multiple sclerosis (MS)
Endpoint: Increase in the time to progression of the disease as measured by the Expanded Disability Status Scale (EDSS) in patients with the genes HLA-DR2 or HLA-DR4
Status: Phase II/III ongoing
Milestone: Interim Phase II/III data (1H08)

For the fifth time, an independent DSMB recommended continuation of a double-blind, placebo-controlled, international Phase II/III study in 553 patients.

Biota Holdings Ltd. (ASX:BTA), Melbourne, Australia
Product: BTA-798
Business: Infectious
Molecular target: NA
Description: Viral capsid binder
Indication: Treat and prevent human rhinovirus (HRV) infection
Endpoint: Safety; pharmacokinetics
Status: Phase Ib started
Milestone: NA

BTA started a double-blind, ascending-dose, U.K. Phase Ib trial in 32 healthy volunteers.

Ceragenix Pharmaceuticals Inc. (CGXP), Denver, Colo.
Product: Epiceram
Business: Dermatology
Molecular target: Not available
Description: Topical, non-steroidal combination of lipids to form a skin barrier
Indication: Treat moderate to severe eczema
Endpoint: EZEASI score, SCORAD score, OSSAD score, reduction in trans-epidermal water loss, visual and patient-assessed symptom improvement
Status: Phase IV started
Milestone: Phase IV data (4Q06); start market launch (1Q07)

CGXP started a non-inferiority, U.S. Phase IV trial in 90 children between the ages of 6 months and 18 years comparing EpiCeram to mid-strength steroids.

Clavis Pharma ASA (OSE:CLAVIS), Oslo, Norway
Product: Elacyt (CP-4055)
Business: Cancer
Molecular target: DNA polymerase
Description: Lipid Vector Technology (LVT) derivative of cytarabine (Ara-C)
Indication: Treat first-line stage III and IV malignant melanoma
Endpoint: Tumor response rate; time to progression, duration of tumor response and safety
Status: Phase II delayed
Milestone: NA

Clavis said the patient enrollment in an international Phase II trial in 42 patients will be delayed by 3-6 months due to "unforseen staffing challenges".

Indication: Treat leukemia
Endpoint: Maximum tolerated dose (MTD); safety
Status: Phase I/II started
Milestone: NA

In June, CLAVIS began a U.S. and European Phase I/II trial.

Cytori Therapeutics Inc. (CYTX; FSE:XMPA), San Diego, Calif.
Product: Adipose-derived regenerative cells (ADRC)
Business: Cardiovascular
Molecular target: NA
Description: Adipose-derived regenerative cells
Indication: Treat chronic ischemia
Endpoint: Safety
Status: NA
Milestone: NA

CYTX will start the placebo-controlled, double-blind, dose-escalation, European PRECISE trial in up to 36 patients by early 2007.

Indication: Treat myocardial infarction (MI)
Endpoint: Safety
Status: NA
Milestone: NA

CYTX will start the placebo-controlled, double-blind, dose-escalation, European Phase I APOLLO trial in up to 48 patients by early next year.

deCode genetics Inc. (DCGN), Reykjavik, Iceland
Product: DG051
Business: Cardiovascular
Molecular target: Leukotriene A4 hydrolase (LTA4H)
Description: Leukotriene A4 hydrolase (LTA4H) inhibitor
Indication: Prevent heart attack
Endpoint: Safety and pharmacokinetics
Status: Phase I started
Milestone: Final Phase I data (4Q06)

DCGN started a double-blind, placebo-controlled, dose-escalation, U.S. Phase I trial in about 40 healthy volunteers.

Durect Corp. (DRRX), Cupertino, Calif.
Voyager Pharmaceutical Corp., Raleigh, N.C.
Product: Memryte leuprolide acetate
Business: Neurology
Molecular target: GnRH/LHRH receptor
Description: Leuprolide loaded implants using Durin technology
Indication: Treat mild to moderate Alzheimer's disease (AD)
Endpoint: Change from baseline in ADAS-Cog and ADCS-CGIC at week 50

See next page