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AMERICAN HOME PRODUCTS' "THIRD GENERATION" TPA ENTERING CLINICALS

by The Pink Sheet

AMERICAN HOME PRODUCTS' "THIRD GENERATION" TPA ENTERING CLINICALS in 1988, the company noted in its just-released 1987 annual report. AHP said that its "third generation" tissue plasminogen activator "is longer acting and causes less bleeding" than Genentech's currently marketed TPA product, Activase. The TPA development project is part of a broader thrombolytic R&D program at Wyeth-Ayerst, the annual report indicates. Clinical studies on a "new, low molecular weight heparin that is longer acting and less likely to cause bleeding than standard heparin" were begun in 1987, the firm reports. While Burroughs Wellcome is chasing Genentech's Activase with a recombinant TPA product discovered at Genetics Institute, AHP is one of a number of large, established pharmaceutical firms looking to cut into Genentech's head start with second and third generation TPA products. Abbott and Lilly also are known to be seeking improved thrombolyticagents by tinkering with TPA activity and production. Genentech's recent lawsuit against Abbott may be the first of several such actions as Genentech seeks to protect its franchise and consolidate its patent position against drug manufacturers looking to leap-frog Genentech's TPA product with newer technology. Also in the cardiovascular area, AHP has an agreement with Cal Bio covering atrial natriuretic factor (anaritide) in congestive heart failure. That product is in Phase II study. Further back in the pipeline, AHP is developing a "series" of renin inhibitors for potential use in hypertension and congestive heart failure. Wyeth-Ayerst is building on Cardarone (amiodarone) in the anti-arrhythmic area with two new agents in development: recainam, in Phase III studies and an unnamed Class III anti-arrhythmic compound, which "will be available for testing in 1988 for use in the treatment of severe ventricular arrhythmias." AHP reported that Wyeth-Ayerst now has a total of 20 new

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chemical entities under active study as well as programs to expand uses and dosage forms of established products, such as Inderal, Isordil, and Premarin. AHP increased its R&D spending in 1987 by just under 9% to $247.3 mil. In the CNS area, Wyeth-Ayerst said it has expanded its R&D in order to add products that complement its line of currently marketed compounds, such as Ativan and Serax. "Venlafexine, a fast-acting, potent antidepressant with an improved side effect profile has entered Phase III clinical study," the annual report notes. "Enciprazine, a nonbenzodiazepine anti-anxiety drug licensed from Degussa . . . will enter Phase III clinical study in 1988." The annual report also updates AHP's progress with vinpocetine, licensed from Gedeon Richter, which is now in Phase III trials for Alzheimer's disease, and notes that an unnamed antipsychotic agent entered clinicals late last year for schizophrenia. AHP's lead products from its NSAID and metabolic disease R&D are still awaiting FDA approval. The NSAIDs, Ultradol (etodolac) and Durapro (oxaprozin), have both been pending at FDA for five years or more. The aldose reductase inhibitor Tolrestat (alredase) is also stuck at FDA following an advisory committee decision in 1986 not to recommend approval of the drug in diabetic neuropathy. AHP commented that Tolrestat "continues in active global Phase III development."

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