

PROGRESS REPORT 16

Totelle 1mg

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<p>DATE</p>	<p>4th March, 2003</p>

Current Projects

PAPERS

PROJECT	CLASSIFICATION	TARGET SUBMISSION DATE / JOURNAL	STATUS / ACTION
<p>Paper PC(1) FAST TRACK A study in postmenopausal women of the efficacy on climacteric symptoms of a continuous combined HRT regimen of 1 mg 17β-estradiol and trimegestone versus two regimens containing 1 or 2 mg 17β-estradiol and norethisterone acetate</p>	Efficacy	February 2003	First draft submitted for initial review August 7 Comments received from Daniele December 7 Revised draft submitted January 3 Final draft submitted for review February 3 Comments received from Daniele, Richie February 28 Final paper being prepared for sign off
<p>Paper PC(2) FAST TRACK A comparison of the effects of continuous combined regimens of 1 mg 17β-estradiol and trimegestone with regimens containing 1 or 2 mg 17β-estradiol and norethisterone acetate upon the bleeding profile and endometrial safety in postmenopausal women</p>	Endometrium/safety	March 2003	First draft submitted for initial review August 19 Comments received from Daniele December 7 Revised draft submitted January 3 Comments received from Sophie February 5 Revised draft submitted to Gary February 28 Comments received from Richie, February 28
<p>Paper PC(3) Metabolic and hemostatic profile of postmenopausal women receiving a continuous combined regimen of either 1mg estradiol with trimegestone or estradiol and norethisterone acetate over a 1-year period</p>	Hemostasis/metabolic impact	April 2003	First draft submitted for initial review April 4, 2002 Comments received from Gary May 13 Revised draft in preparation
<p>Paper PS(1) FAST TRACK A study of the control of climacteric symptoms in postmenopausal women following sequential regimens of 1mg estradiol and trimegestone compared with a regimen containing estradiol and norethisterone over a period of 2 years</p>	Climacteric symptoms	March 2003	First draft submitted for initial review August 8 Comments received from Daniele December 7 Revised draft submitted January 9 Comments received from Richie, February 28 Waiting for comments from Daniele and Sophie

PROJECT	CLASSIFICATION	TARGET SUBMISSION DATE /JOURNAL	STATUS / ACTION
Paper PS(2) FAST TRACK A comparative 2-year study of the effects of sequential regimens of 1 mg estradiol and trimegestone with a regimen containing estradiol and norethisterone upon the patterns of endometrial bleeding and safety in postmenopausal women	Endometrium/safety	March 2003	First draft submitted for initial review August 9 Comments received from Daniele December 7 Revised draft submitted January 13 Comments received from Richie February 28 Waiting for comments from Daniele and Sophie
Paper PS(3) Metabolic and hemostatic profile of postmenopausal women receiving a combined sequential regimen of either 1mg estradiol and trimegestone or estradiol and norethisterone over a 1-year period	Hemostasis/metabolic impact	April 2003	First draft submitted for initial review April 19, 2002 Comments received from Gary May 13 Revised draft in preparation

SUPPORTING ACTIVITIES

PROJECT	TARGET PUBLICATION DATE	STATUS / ACTION
Totelle Monograph 1 and 2mg	March 2003	Completely revised manuscript and figures submitted to Richie January 24
Totelle 1 mg and 2 mg Slide Set on CD-ROM	March 2003	Completely revised slides and notes submitted to Richie February 4

POSTERS

PROJECT	TARGET PUBLICATION DATE	STATUS / ACTION
A24 Psychofunctional and quality-of-life parameters in postmenopausal women receiving continuous combined regimens of either 1 mg 17 β -estradiol/trimegestone, 1 mg estradiol valerate/norethisterone acetate, or 2 mg estradiol valerate/norethisterone acetate: results from a 2-year study	EMAS May 24-28	EMAS submission of abstract on January 20 Acceptance February 14 Poster text in preparation
A37 Body weight changes in postmenopausal women treated with sequential regimens of either 17 β -estradiol combined with trimegestone or comparator combinations containing estradiol and progestin	EMAS May 24-28	EMAS submission of abstract on January 20 Acceptance February 14 Poster text in preparation