Background on the Evolocumab Pregnancy Exposure Registry

- Amgen is sponsoring a Pregnancy Exposure Registry* as required by the United States Food and Drug Administration (US FDA) to evaluate adverse pregnancy outcomes associated with exposure to evolocumab during pregnancy
- Evolocumab is indicated as an adjunct to diet and maximally tolerated statins for use in adults with clinical atherosclerotic cardiovascular disease (ASCVD) and in those with familial hypercholesterolemia (FH) who require additional lowering of LDL-C
- FH occurs in women of reproductive age; therefore it's in this population that exposure to evolocumab during pregnancy is most likely to occur
- The Registry is being conducted by the Organization of Teratology Information Specialists (OTIS), with MotherToBaby (https://mothertobaby.org) as the patient-facing service
- Women are currently being recruited from the US and Canada
- Women will not be asked to change their routine healthcare or healthcare providers

*https://clinicaltrials.gov/ct2/show/NCT02957604).

Target enrollment

- 375 pregnant women over 10 years
  - 75 evolocumab exposed
    - Defined as any number of days, at any dose, and at any time from the first day of the LMP up to and including the end of pregnancy)
  - 150 with FH or hypercholesterolemia and ASCVD
    - This is the disease comparison cohort
  - 150 without FH or hypercholesterolemia and ASCVD
    - This is the non-disease comparison cohort
- Enrollment will take place between 2016-2026
- Women and their live-born offspring will be followed for up to 5 years

How subjects are enrolled into the Registry

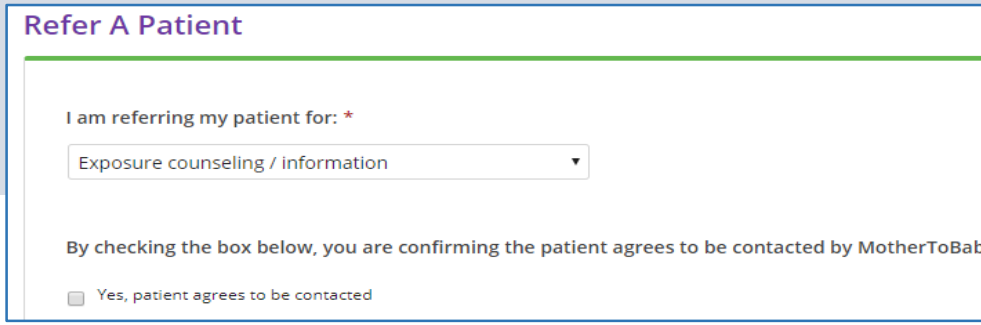
- Subject-initiated enrollment
- Toll free number for North America (used for all MotherToBaby studies)

877-311-8972

- Pregnant women can enroll upon contacting MotherToBaby, at which time eligibility will be determined

HCP-initiated enrollment options are available on the MotherToBaby website*:

1. Via telephone 866-626-6847
2. Via text 855-999-3525
3. Service fax referral form
4. Online Physician Referral Form



*http://mothertobaby.org/healthcare-professional-referral-form/