Positive results of Phase 3 trial of 1-year contraceptive vaginal ring presented

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Today, the Population Council presented findings from a Phase 3 clinical trial that was designed to demonstrate the safety, efficacy, and acceptability of the Council's investigational one-year contraceptive vaginal ring (CVR). The results were presented during an oral session at the 69th Annual Meeting of the American Society of Reproductive Medicine.

The study presented today (Study 300B) is part of an extensive clinical trial package that will be submitted as part of a New Drug Application to the U.S. Food and Drug Administration. The application will include two pivotal Phase 3 clinical trials conducted with more than 2,000 women across 27 study sites worldwide. Study 300B evaluated the contraceptive efficacy, safety, and acceptability of the CVR, and Study CCN006/300A evaluated efficacy and safety. The studies were conducted in partnership with the U.S. Agency for International Development (USAID); the World Health Organization (WHO); and the National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Contraceptive Discovery and Development Branch.

Study 300B was a multicenter, open-label trial that involved more than 1,100 healthy, normally ovulating women across 12 study sites in Australia, Europe, Latin America, and the United States. Preliminary results suggested that the CVR—a type of long-acting, reversible contraceptive (LARC)—is as effective as other combined hormonal contraceptives in preventing pregnancy when used as directed.

Preliminary results also suggested that the safety profile is consistent with that of available combined hormonal contraceptives.

In addition to evaluating contraceptive efficacy and safety, Study 300B assessed women's acceptance of the CVR. The study found that women were highly satisfied with the ring, found it easy to use, and indicated that they would recommend it to other women. The ring was also well-accepted by their partners.

"These results add to the growing body of evidence supporting the use of the Council's investigational one-year contraceptive vaginal ring," said Ruth Merkatz, Ph.D., Director of Clinical Development for the Population Council's Reproductive Health Program. "If approved by regulatory authorities, the ring will offer a unique contraceptive option: a contraceptive that is effective for one full year, is under the woman's control, and does not require insertion by a health care professional."

Because the ring is effective for 13 consecutive cycles (one year) and is intended to not require refrigeration, it may be an attractive option for women in developing countries who lack convenient access to a health care facility or pharmacy, and in areas where access to reliable electricity is a challenge. Significant barriers prevent many women in developing countries from accessing a full range of contraceptive methods to meet their individual needs. These barriers may include a lack of trained providers, supply shortages, storage and electricity limitations, resistance from families or communities, and misconceptions about side effects.

"Our mission is to develop and help expand access to contraceptive technologies where high-quality, voluntary family planning services are scarce or nonexistent," said Peter Donaldson, President, Population Council. "The Council's one-year contraceptive vaginal ring is a promising new technology. We look forward to furthering its

development to meet the needs of underserved women."

Provided by Population Council