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Good morning. My name is Lisa Schlager and I am pleased to speak on behalf of FORCE, the only national nonprofit organization devoted to people and families affected by hereditary cancers. We have been providing support, advocacy, education, and research to this community for over 20 years.

For disclosure: FORCE has received financial support from AstraZeneca for our annual conference and other education programs. The company also provided support for advertising clinical trials enrolling patients with hereditary cancer. AstraZeneca does not have input into the content of any of our programs and no sponsors or financial supporters influenced these comments.

Pancreatic cancer is the 3rd leading cause of cancer-related death in the U.S. and its incidence is on the rise. It is one of the few cancers for which survival has not improved substantially for more than 40 years. For all stages combined, over 90% of pancreatic cancer patients die within five years of diagnosis. Few risk factors for developing pancreatic cancer have been identified, but BRCA mutation carriers are known to be at increased risk.

People with BRCA mutations face some of the highest known cancer risks of any population. Their cancers develop at younger ages and the mutation often affects multiple family members, who pass their inherited mutation on to future generations. This community faces a disproportionate cancer burden. However, the unique biology of BRCA-mutated cancer cells offers potential therapeutic advantages. Adoption of therapies that target the cancers in mutation carriers makes sense. In fact, new NCCN guidelines stress that everyone diagnosed with pancreatic cancer should undergo genetic testing for germline mutations.

For the hereditary cancer community and millions of people we represent, therapies targeting BRCA and other mutation-associated cancers offer hope. FORCE first learned about PARP inhibitors over a decade ago. Since that time, we have followed the research, educated our community about these agents, and facilitated clinical trial enrollment. Our community is very motivated to participate in research. Still, completion of PARP studies has taken a long time and



in the interim, many people who could not access these agents and did not meet clinical trial criteria have died.

While the POLO trial demonstrated a modest overall benefit to patients, with 20% of those receiving olaparib experiencing partial or complete tumor shrinkage, the benefit was quite extraordinary for this subset of patients—with some deriving years of time off of chemotherapy. The ORR in the olaparib arm was about 23% versus 11.5% with placebo, and 2 patients receiving olaparib achieved a complete response. Median duration of response was 7.4 months in the olaparib arm, compared to 3.7 months in the placebo arm.

Although overall survival was unchanged in the POLO trial, those who received olaparib benefitted from twice as much time off of chemotherapeutic drugs. This is notable because quality of life tends to be much better for patients when they are not on chemotherapy.

Pancreatic cancers in people with germline BRCA mutations are more likely to respond to platinum-based chemotherapy drugs—but chemotherapy can have many side effects, some of which intensify over time. Maintenance therapy provides these patients with a chemo-free interval.

David Dessert, a BRCA2+ pancreatic cancer survivor diagnosed in 2011, shared the following: “Pancreatic cancer is a disease that predominantly affects an older population that is unwilling or unable to tolerate the harsh treatments that are most effective. For those healthy enough to tolerate them, neuropathy develops quickly causing patients to drop the platinum component. A PARP inhibitor could alleviate all of this as an effective platinum replacement while reducing the toxicities, and improving and increasing the quality of remaining life.”

David’s father, an Air Force veteran with the retiring rank of Lt. Col., died from BRCA-related pancreatic cancer earlier this year.

POLO gives us confirmation that PARP inhibitors are active in BRCA-related pancreatic cancer. Research should continue to determine how to optimize their use. In the meantime, use as maintenance therapy is an important step forward for these patients.



People fighting pancreatic cancer need every benefit they can get. Olaparib gives BRCA mutation carriers more time without disease and more time where they can avoid chemotherapy, translating to months or years with improved quality of life.

FORCE strongly supports FDA approval of olaparib as maintenance therapy for BRCA+ metastatic pancreatic cancer. We also want to note that PARPs are working in BRCA-related cancers regardless of location; these patients need access as well. We firmly believe that this therapy will better the lives of BRCA+ patients fighting this deadly disease.

