SYNOPSIS

Name of Sponsor/Company	Janssen Research & Development*
Name of Finished Product	PRILIGY®
Name of Active Ingredient(s)	R096769 (dapoxetine hydrochloride)

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Status: Approved

Date: 14 December 2012

Prepared by: Janssen Research & Development, LLC

Protocol No.: R096769-PRE-4001

Title of Study: A Prospective, Observational Study of Men With Premature Ejaculation Who Are Treated With PRILIGY™ or Alternate Care

The PAUSE Study (Premature Ejaculation - Actual Use Safety and Effectiveness Study)

EudraCT Number: 2009-011309-18

NCT No.: NCT01021670

Clinical Registry No.: CR016477

Coordinating Investigator(s): Prof. Vincenzo Mirone, University of Naples Federico II, Policlinico "Federico II", Via S. Pansini 5, 80131 - Naples, Italy

Study Center(s): The study was conducted at 414 sites (Italy=117 sites, Germany=159 sites, Spain=110 sites, Finland=6 sites, Portugal=13 sites, Sweden=6 sites, Austria=3 sites).

Publication (Reference): None

Study Period: 22 September 2009 to 07 September 2012

Phase of Development: Phase 4

Objectives: The primary objective of this study was to characterize the safety profile of PRILIGY when used in routine clinical practice to treat men with premature ejaculation (PE).

The secondary objectives were:

- To identify the proportion of patients who were selected to receive PRILIGY who reported a history of an orthostatic reaction and/or had a positive orthostatic test
- To study the patterns of PRILIGY use (e.g., discontinuation rate, dosage change, consumption)
- To describe the characteristics of patients in the PRILIGY and alternate care/non-PRILIGY groups in relation to relevant PRILIGY labeling (e.g., Contraindications or Special warnings and precautions for use)

- To study the pattern of use and safety profile of alternate care/non-PRILIGY treatment(s) used to treat patients with PE in clinical practice
- To gain input from patients and participating health care providers (HCPs) as to the understandability and adequacy of the PRILIGY Patient Information Leaflet (PIL) and/or Patient Brochure

No formal hypothesis was tested in this study.

Methodology: This was an approximately 12-week, prospective, postmarketing, observational study with a 4-week post-observational telephone follow-up contact to collect and evaluate safety data for the labeled use of PRILIGY and alternate care/non-PRILIGY treatment (defined as any treatment other than the on-label use of PRILIGY [e.g., oral, topical, or behavioral]), which were prescribed and/or recommended in routine clinical practice for men with a diagnosis of PE in those countries where PRILIGY had received initial marketing authorization (i.e., Austria, Finland, Germany, Italy, Portugal, Spain, Sweden) through the Decentralized Procedure that was completed in December 2008. The study consisted of 3 periods, including a pre-observational period with a screening/baseline visit on Day 1, an observational period consisting of approximately 3 study visits (defined as Visits 2 to 4) that were anticipated over a period of approximately 12 weeks, although patients were instructed to return for study visits according to local practice, and a post-observational period, which consisted of a telephone follow-up contact approximately 4 weeks after the end of treatment/early withdrawal visit. The intent of the study was to observe and collect data from the participating HCP in the treatment of men with PE in accordance with local practice, although the Summary of Product Characteristics (SPC) for PRILIGY, including recommendations regarding the intended use of PRILIGY (e.g., SPC Posology and method of administration, Contraindications, and Special warnings and precautions for use), was provided in the study protocol. All treatment decisions (i.e., PRILIGY or alternate care/non-PRILIGY) were made at the discretion of the participating HCP.

Number of Patients (planned and analyzed): An estimated 12,000 men with PE (approximately 6,000 patients per group) were to be enrolled in the study, with a minimum of approximately 6,000 patients treated with PRILIGY. The sponsor had the option to discontinue further enrollment once 6,000 patients were enrolled in the PRILIGY group. A total of 10,028 patients were included in the All Enrolled Patients Analysis Set with 6,712 (67.6%) patients selected for treatment with PRILIGY and 3,316 (32.4%) patients selected for treatment with alternate care/non-PRILIGY. Among the All Enrolled Patients Analysis Set, 9,443 (94.2%) patients were included in the Safety Analysis Set, of which 6,128 (91.3%) patients and 3,315 (>99.9%) patients were selected for treatment with PRILIGY and alternate care/non-PRILIGY, respectively.

Diagnosis and Main Criteria for Inclusion: No specific selection criteria (inclusion or exclusion criteria) were specified to select patients, due to the observational nature of this study. Patients were considered for enrollment in the study only after the participating HCP had determined that either treatment with PRILIGY, based on the prescribing information in the SPC, or alternate care/ non-PRILIGY treatment was appropriate. Only patients with a current diagnosis of PE, or who were newly diagnosed with PE, and who sought treatment for their condition (i.e., patients who presented spontaneously for evaluation and were not actively recruited by the participating HCP) were considered for enrollment in the study. To maintain the observational nature of the study, the participating HCP was instructed not to discuss the possibility of study participation with the patient until after there was an agreement between the participating HCP and the patient as to the appropriate course of treatment.

Test Product, Dose and Mode of Administration, Batch No.: Neither PRILIGY nor alternate care/ non-PRILIGY treatment was supplied by the sponsor in this study. The participating HCP prescribed either PRILIGY or alternate care/non-PRILIGY treatment after an initial evaluation of the patient during

the pre-observational period. Patients who were treated with PRILIGY should have received educational information in the form of the PIL and Patient Brochure for PRILIGY, while the participating HCP was to follow prescribing information in accordance with the recommendations for use in the SPC for PRILIGY.

Reference Therapy, Dose and Mode of Administration, Batch No.: Alternate care/non-PRILIGY treatment was not supplied by the sponsor in this study. The participating HCP prescribed alternate care/ non-PRILIGY treatment after an initial evaluation of the patient during the pre-observational period. Patients who were treated with alternate care/non-PRILIGY treatment were instructed to take or use the treatments as prescribed and directed by the participating HCP.

Duration of Treatment: PRILIGY or alternate care/non-PRILIGY treatment was used on an as-needed basis for approximately 12 weeks.

Criteria for Evaluation:

SAFETY

Measurement of Orthostatic Vital Signs

Orthostatic vital signs (blood pressure and heart rate [pulse]) were measured during the pre-observational period for patients who were candidates for treatment with PRILIGY. The following approach was recommended as an acceptable method for measuring orthostatic vital signs:

- The first measurement should be taken with the patient in the supine position for at least 2 minutes, and recorded.
- The second measurement should be taken with the patient in the standing position (or sitting position if unable to stand) for at least 2 minutes after the supine measurements but before 3 minutes, and recorded.

Adverse Events

Safety and tolerability were evaluated throughout the study by incidence, severity, and type of adverse events, serious adverse events, adverse events of special interest, and physical examination results (at screening/baseline, and at any other time during the study that the participating HCP deemed it medically necessary). Safety was reviewed on a regular basis by an internal safety working group to detect potential safety signals associated with the use of PRILIGY in the post-approval setting.

Syncope was identified as an adverse event of special interest in this study. In addition to syncope, other adverse events that were reported on the Adverse Event Case Report Form (CRF) were classified in the Statistical Analysis Plan (SAP) as adverse events of special interest according to the identified and potential risks identified in the Risk Management Plan (RMP) for PRILIGY (Mood and Related, Neurocognitive Related, Cardiovascular System, Urogenital System and Sexual Function, Accidental Injury, Abnormal Bleeding, and Others). Such events were identified through a search of all adverse event terms in the clinical database using the same search strings that were developed for previous clinical study reports and the Summary of Clinical Safety. An independent Syncope Adjudication Committee (SAC) was established to adjudicate possible events of syncope as to whether or not loss of consciousness had actually occurred.

Statistical Methods: Statistical analyses were exploratory and descriptive in nature. All statistical considerations, including derived variables, proposed format, and content of tables was detailed in the SAP. The All Enrolled Patients Analysis Set was defined as all patients for whom information was entered into the database. All patients who took at least one dose of PRILIGY were included in the Safety

Analysis Set associated with PRILIGY treatment, while all patients who did not use PRILIGY at Visit 1 and used alternate care/non-PRILIGY treatment at Visit 1 were included in the analysis associated with alternate care/non-PRILIGY treatment.

A patient was considered to have completed the study if he had completed the end-of-observation assessments during the observational period. Patients who prematurely discontinued study treatment (PRILIGY or alternate care/non-PRILIGY) for any reason before completion of the observational period (approximately 3 study visits [defined as Visits 2 to 4] were anticipated over a period of approximately 12 weeks) were not considered to have completed the study.

While patterns of use and safety data were collected for both treatments, the patient characteristics between the groups were expected to be different because of 1) possible selection bias in the determination of treatment (e.g., orthostatic testing, comorbidities, and prior treatment history might have formed the basis for the treatment decision), 2) the diversity of treatments prescribed in the alternate care/non-PRILIGY group, and 3) contraindications associated with PRILIGY and the different alternate care/non-PRILIGY treatment options. All of these factors increase the likelihood of bias, while the same patient population characteristics/demographics were not necessarily expected to be similar among both groups (PRILIGY and alternate care/non-PRILIGY). Therefore, such circumstances would challenge the interpretation of the results of any direct statistical comparison. Several subpopulations of patients sharing common characteristics (e.g., patient age, medical history of cardiovascular or psychiatric conditions) however were identified, such that safety data observed in the alternate care/non-PRILIGY group could provide perspective among the incidence of adverse events among patients who were treated with PRILIGY.

No formal interim analyses were planned for this study, however interim safety data reviews were conducted periodically as noted in the SAP, while one interim safety report was issued and submitted to health authorities in response to regulatory review during the course of the study.

PLANNED ANALYSES

Descriptive statistics (e.g., mean, standard deviation, median, minimum, maximum, range) of baseline information for each group was provided for continuous variables (e.g., age, number of days of treatment). Counts and appropriate percentages for each group were provided for categorical variables, which included, but were not limited to those variables that represented comorbidities and/or concomitant therapies that should have been avoided with PRILIGY administration, such as significant pathologic cardiac conditions, severe renal impairment, moderate or severe hepatic impairment, depression, anxiety, mania, schizophrenia, use of potent cytochrome P450 (CYP) 3A4 inhibitors, and antidepressants. Due to precautions related to the possibility of reduced orthostatic tolerance, the frequency of use of alpha-adrenergic receptor antagonists and phosphodiesterase Type 5 inhibitors (PDE5Is) were also evaluated, while the number of patients who underwent orthostatic testing before the prescribing of PRILIGY and the test results of all patients who were administered orthostatic testing were summarized. Associations between orthostatic test results and the occurrence/non-occurrence of syncope and cardiovascular adverse events were summarized. In addition, the patterns of PRILIGY dose escalation (from 30 to 60 mg) status was summarized with respect to the orthostatic test result before the prescription of PRILIGY.

The patterns of drug use (e.g., discontinuation rate, dosage change, and consumption) were summarized descriptively for each group as appropriate.

The survey results that were collected (from patients at the last observational visit and from participating HCPs after the last patient had completed the observational period) to provide feedback on the

understandability and adequacy of the PRILIGY Patient Brochure and/or PIL was summarized by patient and participating HCP.

Safety

The original terms used in the CRF by participating HCPs to identify adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA), Version 15.0. The percentage of patients with specific treatment-emergent adverse events (TEAEs), as well as the severity of adverse events was summarized for each group. Adverse events were summarized based on treatment group and by subgroup within patients receiving alternate care/non-PRILIGY treatment(s), including alternate care (oral drug) and alternate care (non-oral drug) treatment. In addition, the incidence rate based on person-time of exposure (and per-dose administration) was presented. The 95% confidence interval (CI) for adverse events of special interest (e.g., syncope) and serious adverse events was provided.

The primary objective of the study was to determine the safety profile of PRILIGY when used in routine clinical practice. Because of the potential for systematic patient channeling, a direct comparison of safety event rates between patients treated with PRILIGY and patients treated with alternate care/non-PRILIGY treatment(s) is considered likely to be inherently biased. To minimize this bias, any attempt to evaluate the difference in the incidence of adverse events of special interest between treatments (PRILIGY or alternate care/non-PRILIGY) were evaluated using logistic and Poisson regression, adjusting for potential confounding factors such as age group, history of significant cardiac conditions, history of depression and other psychiatric comorbidities, and concomitant therapies identified in the descriptive analyses.

- All reported adverse events with onset during the observational period (i.e., TEAEs) were included in the analysis. For each adverse event, the percentage of patients who experienced at least one occurrence of the given event was summarized by group.
- Special attention was given to those patients who died, discontinued treatment due to an adverse event, or who experienced a severe or serious adverse event (e.g., summaries, listings, and narratives were provided, as appropriate).

To investigate if participating HCPs minimized the use of PRILIGY in patients specified in the Contraindications, Special warnings and precautions for use, and Interactions with other medicinal products in the SPC, the proportion of patients who presented with these characteristics relevant to PRILIGY prescription who were selected for PRILIGY treatment were summarized.

CHANGES IN PLANNED ANALYSES

Safety

Subgroups of PRILIGY and alternate care/non-PRILIGY patients with common characteristics were to be selected if any populations at risk were identified. Because the reported incidence of certain adverse events (e.g., syncope) was rare (PRILIGY, 0 patients; alternate care/non-PRILIGY, 1 patient [<0.1%]), no attempt was made to determine the statistical differences between treatments (PRILIGY or alternate care/non-PRILIGY) via logistic or Poisson regression modeling adjusting for potential confounding factors.

RESULTS:

STUDY POPULATION:

Of the 9,443 patients included in the Safety Analysis Set, a total of 8,561 (90.7%) patients completed the study. In general, there were no clinically important differences in the discontinuation rate between patients who were treated with PRILIGY and those who were treated with alternate care/non-PRILIGY. The percentage of patients who discontinued the study was greater in those who were treated with PRILIGY (10.9%) than those who were treated with alternate care (oral drug) (6.9%) or alternate care (non-oral) treatment (6.0%). Overall, the most common reasons for discontinuation were lost to follow-up (3.5%), personal reason (2.4%), insufficient response (1.6%), and adverse event (1.0%), while the proportion of discontinuations was generally greater in those patients who were treated with PRILIGY (3.9%, 2.7%, 2.1%, 1.5%, respectively) than in those who were treated with alternate care (oral drug) (2.5%, 1.8%, 1.0%, 0.4%, respectively), or alternate care (non-oral) treatment (2.8%, 1.6%, 0.4%, and 0.1%, respectively).

In general, there were no apparent differences in demographic or baseline characteristics between the 2 groups (PRILIGY or alternate care/non-PRILIGY). The mean age for all patients was 40.5 years, with most patients included in the age groups of 30 to 39 years (28.0%) and 40 to 49 years (27.0%). A total of 186 (1.9%) patients were ≥65 years of age and 2 (<0.1%) patients under the age of 18 were enrolled. The majority (96.0%) of patients were White, while the racial proportions in each treatment group were similar. The 2 groups were generally similar among the categories of PE diagnosis (i.e., lifelong versus acquired).

The majority of patients who were treated with PRILIGY had baseline characteristics that were consistent with the recommendations in the SPC for PRILIGY; most of the patients who were treated with PRILIGY were <65 years of age and did not have a history of an orthostatic reactions (98.1% and >99.9%, respectively). The frequency of alcohol use was similar between those patients who were treated with PRILIGY and those patients who were treated with alternate care/non-PRILIGY.

The overall prevalence of cardiovascular disorder diagnoses identified from the medical history at baseline was slightly greater in patients who were treated with PRILIGY (10.3%) than in those patients who were treated with alternate care/non-PRILIGY (9.7%) when hypertension was included, and was similar for patients who were treated with PRILIGY (2.4%) and for those patients who were treated with alternate care/non-PRILIGY (2.5%) when hypertension was excluded. Overall, the incidence of TEAEs was greater in patients who were treated with PRILIGY, with or without a medical history of cardiovascular disorders (18.6% and 11.3%, respectively) than in patients who were treated with alternate care/non-PRILIGY, with or without a medical history of cardiovascular disorders (13.4% and 8.4%, respectively). Overall, a total of 12 patients with cardiovascular disorder diagnoses identified from the medical history at baseline reported a serious adverse event, all of which were not considered related to treatment with the study drug by the participating HCP. One patient with a history of syncope who was treated with alternate care/non-PRILIGY reported a serious adverse event of B-cell lymphoma.

A total of 466 (6.9%) patients with a psychiatric disorder were treated with PRILIGY. The overall prevalence of psychiatric disorder diagnoses identified from the medical history at baseline was 6.9% in patients who were treated with PRILIGY and 11.0% in patients who were treated with alternate care/ non-PRILIGY. Overall, the incidence of TEAEs was greater in patients who were treated with PRILIGY, with or without a medical history of psychiatric disorders (11.3% and 12.1%, respectively) than in patients who were treated with alternate care/non-PRILIGY with or without a medical history of psychiatric disorders (7.7% and 9.0%, respectively). Overall, a total of 3 patients with psychiatric disorder diagnoses identified from the medical history at baseline reported a serious adverse event; one patient treated with PRILIGY reported a serious adverse event of constipation, while the other 2 serious adverse

events were reported by patients who were treated with alternate care/non-PRILIGY (one depression and one gallbladder disorder).

Evaluation for an orthostatic reaction at baseline, which was undertaken only for those patients who were candidates for treatment with PRILIGY, revealed such a reaction in 70 (1.0%) of patients. Sixty of the 70 patients were included in the Safety Analysis Set; 6 of the 70 patients did not take a dose of PRILIGY, while 4 of the 70 patients had only a first visit.

A total of 58 (0.9%) patients who were treated with PRILIGY had been prescribed a contraindicated concomitant therapy during the course of the study; antidepressants represented the class of contraindicated therapies used most often by patients who were treated with PRILIGY. A total of 540 (8.8%) patients who were treated with PRILIGY used a concomitant medication with Special warnings and precautions for use when used with PRILIGY during the course of the study; PDE5Is (5.5%) and alpha-adrenergic receptor antagonists (3.3%) were the most commonly used concomitant medications with those Special warnings and precautions for use.

A total of 9 (0.3%) patients who were treated with alternate care/non-PRILIGY had a protocol deviation. No protocol deviations were reported for patients who were treated with PRILIGY.

The mean duration of the treatment period was similar between those patients who were treated with PRILIGY and those patients who were treated with alternate care/non-PRILIGY (88.2 days versus 87.0 days, respectively). The total number of PRILIGY doses taken ranged from 1 to 54 doses. The overall majority of patients (61.8%) took no more than 10 doses during the treatment period, while the total mean number of PRILIGY doses taken during the treatment period was 10.2.

In accordance with the SPC, 5,697 (93.0%) patients were initially prescribed PRILIGY 30 mg whereas 431 (7.0%) patients were initially prescribed the 60-mg dose. The majority of the patients continued with the 30-mg dose at Visits 2, 3, and 4 (82.4%, 77.8%, and 76.9%, respectively). An increase in the dose from 30 to 60 mg of PRILIGY occurred most frequently at Visit 2 (10.6%), whereas among 431 patients who were taking 60 mg at Visit 2, 36 (8.3%) patients decreased the dose from 60 to 30 mg. Of the total number of patients who provided a rationale for dose adjustments, the majority of patients increased the dose from 30 to 60 mg of PRILIGY at Visits 2, 3, and 4 due to insufficient response (82.8%, 79.4%, and 77.9%, respectively), and the majority of patients decreased the dose from 60 to 30 mg of PRILIGY at Visits 2, 3, and 4 due to patient preference (50.0%, 47.4%, and 53.6%), respectively.

EFFICACY RESULTS:

Efficacy was not assessed in this study.

SAFETY RESULTS:

Overall, TEAEs were reported by 12.0% and 8.9% of patients who were treated with PRILIGY and alternate care/non-PRILIGY, respectively. The incidence of TEAEs was greatest for patients who were treated with alternate care (oral drug) (16.1%), and lowest for patients who were treated with alternate care (non-oral) treatment (3.5%). Adverse events were most commonly reported in the gastrointestinal disorders and nervous systems disorders system organ classes (SOCs). Overall, the most commonly reported TEAEs (≥1% in any group) were nausea (2.4%), headache (1.9%), and vertigo (0.8%), with a higher incidence in patients who were treated with PRILIGY (3.1%, 2.6%, and 1.0%, respectively) than in patients who were treated with alternate care (oral drug) (2.3%, 1.3%, and 0.9%, respectively) or alternate care (non-oral) (0.1%, 0.3%, and 0%, respectively). The majority of TEAEs reported in either group was mild or moderate in severity, resulted in no change in treatment, and was resolved by the time that the patient completed or withdrew from the study.

The overall incidence of TEAEs was greater in patients who increased their dose of PRILIGY from 30 to 60 mg (15.0%) than those who remained on the 30-mg dose for the duration of the study (10.9%). The incidence of TEAEs was reported more frequently (12.9%) for those who were titrated to PRILIGY 60 mg at Visit 2 than for those who remained on PRILIGY 30 mg for the duration of the study (4.8%), although for those who remained on PRILIGY 60 mg at Visits 3 and 4, the incidence of TEAEs was less at Visit 2 (10.5% and 8.7%, respectively). Treatment-emergent adverse events were most frequently reported in the gastrointestinal disorders and nervous system disorders SOCs, with a greater incidence in patients who increased the dose of PRILIGY from 30 to 60 mg (5.4% and 5.2%, respectively) than those who remained on the 30-mg dose of PRILIGY for the duration of the study (4.2% and 3.6%, respectively).

At Visit 2, the incidence of adverse events was similar, but less severe, for patients who had their dose of PRILIGY increased from 30 to 60 mg compared with those who remained on the 30-mg dose for the duration of the study (6.3% versus 7.0%, respectively). In addition, patients who were titrated to PRILIGY 60 mg at Visit 2 had a lower incidence of possibly prodromal adverse events than those who remained on the 30-mg dose for the duration of the study (2.0% versus 2.4%), while patients who were down titrated from 60 to 30 mg of PRILIGY reported a greater incidence of TEAEs than those who remained on either 30 or 60 mg of PRILIGY for the duration of the study.

The overall incidence of TEAEs was greater in patients who were ≥65 years of age (21.4%, PRILIGY; 7.5%, alternate care/non-PRILIGY) than in patients who were <65 years of age (11.9%, PRILIGY; 8.9%, alternate care/non-PRILIGY), although the sample sizes were small. Among the patients who were treated with PRILIGY, vertigo and fatigue were reported at a greater incidence in patients who were ≥65 years of age (3.1% and 2.0%, respectively) than in those patients who were <65 years of age (1.0% and 0.3%, respectively). No TEAEs were reported in patients who were ≥65 years of age and received alternate care (non-oral) treatment.

There were no reports of death among patients who were treated with either PRILIGY or those who were treated with alternate care/non-PRILIGY in the study. A total of 22 patients in the Safety Analysis Set reported treatment-emergent serious adverse events during the study, 12 (0.2%) patients treated with PRILIGY and 10 (0.3%) patients treated with alternate care/non-PRILIGY. All of the serious adverse events were considered not related to treatment with PRILIGY or alternate care/non-PRILIGY by the participating HCPs.

The incidence of patients that discontinued from the study due to a TEAE was greater in patients who were treated with PRILIGY (1.5%) than in patients who were treated with alternate care/non-PRILIGY (0.2%), although no TEAE led to the discontinuation of more than 0.3% of patients in either treatment group. Of the TEAEs of special interest, nausea, hypotension, dizziness postural, orthostatic hypotension, and presyncope resulted in discontinuation in patients who were treated with PRILIGY only, although the incidence of discontinuations resulting from each of these TEAEs was low (0.3%, <0.1%, <0.1%, <0.1%, and <0.1%, respectively).

Overall, the total incidence of TEAEs of special interest in each of the adverse event categories was low. Treatment-emergent adverse events of special interest were most commonly reported in the neurocognitive-related adverse event category (2.0%). With the exception of the cardiovascular system (PRILIGY, 1.6%; alternate care [oral drug], 1.3%) and accidental injury (0.1%; for both), TEAEs of special interest in each adverse event category was greater for patients who were treated with alternate care (oral drug) than PRILIGY.

There were no associations between TEAEs of syncope and orthostatic test results. One event of syncope was reported as a serious adverse event in a patient who was treated with alternate care/non-PRILGY (paroxetine), which was adjudicated as syncope with loss of consciousness by the SAC. It was reported

by a patient in Finland who presented to the hospital with severe syncope, photophobia, and muscular weakness that he experienced 5 or more days after taking his last dose of paroxetine. The participating HCP did not consider any of the events to be related to his treatment with paroxetine, the events resolved, no action was taken with paroxetine, and the patient completed the study.

STUDY LIMITATIONS:

There were no notable study limitations identified by the sponsor.

CONCLUSION(S):

Overall, the types of adverse events observed in this postmarketing observational study is consistent with the safety profile presented in the SPC for PRILIGY, although the incidence rates of these events are less than those observed during clinical development. Participating HCPs generally followed the prescribing instructions in the SPC by initiating patients on the 30-mg dose of PRILIGY and by selecting patients according to the recommendations in the SPC (e.g., Posology and method of administration, assessing orthostatic tolerance before the initiation of PRILIGY, avoiding the use of PRILIGY in patients who have medical histories or use concomitant medications listed in the Contraindications and Special warnings and precautions for use). However, some patients with cardiovascular or psychiatric conditions contraindicated by the SPC were treated with PRILIGY. The Patient Brochure and PIL were found to be adequate by the large majority of participating HCPs and patients. The low incidence of adverse events and lack of any events of syncope in PRILIGY-treated patients in this large, diverse population of men with PE supports tolerability of PRILIGY when prescribed in routine clinical practice, suggesting that the current risk minimization measures for its identified and potential risks, including syncope, are effective.

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