Clinical Study Synopsis

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### Clinical Trial Results Synopsis

**Study Design Description**

<table>
<thead>
<tr>
<th><strong>Study Sponsor:</strong></th>
<th>Bayer Healthcare AG</th>
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<tbody>
<tr>
<td><strong>Study Number:</strong></td>
<td>0399</td>
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<tr>
<td><strong>Study Phase:</strong></td>
<td>III</td>
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<tr>
<td><strong>Official Study Title:</strong></td>
<td>Efficacy and tolerability of bifonazole cream 1% and solution 1% in dermatomycosis.</td>
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<td><strong>Therapeutic Area:</strong></td>
<td>Anti-Infectives</td>
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**Test Product**

<table>
<thead>
<tr>
<th><strong>Name of Test Product:</strong></th>
<th>Mycospor / Canesten Extra (Bifonazole, BAY H 4502)</th>
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<tr>
<td><strong>Name of Active Ingredient:</strong></td>
<td>Bifonazole</td>
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<tr>
<td><strong>Dose and Mode of Administration:</strong></td>
<td>Topical application of BAY H 4502 (bifonazole) cream 1% or solution 1% to the affected skin once daily, in the evening.</td>
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</table>

**Reference Therapy/Placebo**

<table>
<thead>
<tr>
<th><strong>Reference Therapy:</strong></th>
<th>Not applicable</th>
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</thead>
<tbody>
<tr>
<td><strong>Dose and Mode of Administration:</strong></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Duration of Treatment:**

- Tinea corporis/Tinea cruris–14 days
- Pityriasis versicolor–14 days
- Tinea pedis interdigitalis–21 days
- Superficial candidosis–28 days

**Studied period:**

- **Date of first subjects' first visit:** June, 1986
- **Date of last subjects' last visit:** October, 1987

**Study Centers:**

The study was carried out at 8 sites in Portugal.

**Methodology:**

This was an open-label, multicenter, non-randomized, mycologically controlled study to evaluate the effectiveness and tolerance of Bay 4502 (bifonazole) cream 1% and solution 1% in subjects with dermatomycosis.

Subjects with positive direct microscopic examination prior to treatment and confirmation of microscopic finding by mycological cultural examination were enrolled. Diagnosis of infection with Malassezia furfur was established by Wood's light. Direct microscopic examination and mycological culture examination were repeated three days after treatment (end of treatment) and three weeks after treatment.
**Indication/ Main Inclusion Criteria:**

**Indications:**
- Tinea corporis / Tinea cruris
- Tinea pedis interdigitalis
- Superficial candidosis
- Pitiriasis versicolor

**Inclusion criteria:**
- Positive microscopy findings
- Positive mycological culture findings
- Positive Wood’s light test for Malassezia furfur

**Study Objectives:**

**Overall:**
To evaluate the efficacy and tolerance of Bay 4502 in subjects with dermatomycosis.

**Evaluation Criteria:**

**Efficacy (Primary):**
Therapeutic outcome and disease was evaluated based on:
- Mycological response (potassium hydroxide and culture)
- Wood’s light test
- Clinical findings of reddening, itching, rhagadas, scaling, vesiculation and exudation

**Safety:**
Tolerance to the study drug was observed.

**Statistical Methods:**

**Efficacy (Primary) - if applicable:**
Absolute and relative values of the collective data were determined in terms of minimum/medium/maximum + SD

**Safety:**
Information regarding safety and tolerance was recorded.

**Number of Subjects:**
A total of 333 subjects (190 male and 143 female) were included in the study.

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**Study Results**

**Results Summary — Subject Disposition and Baseline**

The mean age of the subjects was 32.53 years. Bifonazole cream was applied in 65% of the subjects and solution was administered in 35% of the subjects. The duration of infection was more than 6 months for 142 subjects, more than 1 month and less than 6 months for 109 subjects, and up to 1 month for 82 subjects. One hundred thirty-four subjects had Tinea corporis/Tinea cruris, 117 had pitiriasis versicolor, 72 had Tinea pedis interdigitalis, and 13 had superficial candidosis.

**Results Summary — Efficacy**

Efficacy was tested only in subjects with positive cultures or positive Wood light test before the start of treatment. Of 290 subjects, with information about the result of mycological culture or positive Wood light tests after treatment, 266 (91.72%) were negative and 24 (8.27%) were positive.
The cure rates of Bay 4502 for different indications were as follows:

- Tinea corporis / Tinea cruris: 88.1%
- Tinea pedis interdigitalis: 91.5%
- Superficial candidosis: 92.3%
- Pityriasis versicolor: 95.4%

The symptoms that were identified prior to treatment, redness, itching, rhagades, scaling, vesiculation and exudation, resolved in 83%, 92%, 98%, 89%, 96% and 100% of subjects, respectively.

<table>
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<tr>
<th>Results Summary — Safety</th>
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<tbody>
<tr>
<td>The study drug Bay 4502 (bifonazole cream and solution) was tolerated by the subjects. Adverse effects were observed in two subjects: one had reddening and itching and the other had dermatitis.</td>
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<th>Conclusion(s)</th>
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<tr>
<td>In this study, BAY H 4502 cream and solution were effective in treating the studied indications, and subjects tolerated the study drugs.</td>
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<th>Date Created or Date Last Updated:</th>
<th>23 Aug 2011</th>
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