$#"®
(PIMAFUCORT®)

!:;04:
4VNGV @5G>28=8: =0B0:>@B87>=, =5>
1 3 <07V : =0B0 3V4@@>:>@@>@B87>=C 10 <3, =5> 3,5 <3;
4>?>28=0: >;5>35;L ?>;V5B8;5=>289.

V:0@AL:0 D>@<0. 07L.
A=>2=V DV78:>-EVABV: <07L 2V4 1V;>3> 4> A2VB;>-6>2B>3> :>;L>@@@C.

$0@<0:>:>B5@0?52B8G=0 3@C?0. >@B8:>AB5@>W48 4;O 70AB>AC20==O C 45@<0B>;>3VW.
>@B8:>AB5@@@W48 C :><1V=0FVW 7 0=B81V>B8:0<8. >4 "% D07! 01.

$0@<0:>:>;>3VG=V 2;0AB82>ABV.
$0@<0:>:>48=0<V:0
V<0DC:>@B® :><1V=>20=89 ?@5?0@0B, I> 28=8: 3V4@@>:>@B87>=, =5>
V4@@>:>@B87>= :>@B8:>AB5@>W4, I> <0T ?@>B870?0;L=C, AC48=>72C6C20;L=C 4VN; 7<5=HCT
A25@1V6, :89 AC?@>2>46CT @V7=V 2848 45@<0B>7V2.
5>B8:>< H8@>:>:>3> A?5:B@0 4VW, 0:B82=89 I>4> 45O:8E 3@078B82=8E (AB0DV;>:>:V2, 5=B5@>:>:V2)
V 3@0<=530B82=8E (*Klebsiella spp., Proteus spp., Escherichia coli*) 10:B5@V9. *Pseudomonas aeruginosa*
ABV9:0 4> =5>*in vitro.*
0B0 ?>;VT=V8 0=B81V>B8:V2, I> <0T ?@>B83@81:>2C, <0T DC=3VF84=C 4VN; I>4> H5==N 4>
V=D5:FV9, A?@8G8=5=8E 3@810<8, 7>:@5<0 *Candida spp.* 52V4<>, G8 ABV9:V8 4> =0B0
5@5E@5A=0 @578AB5=B=VABL< B0 V<H8<0 0=B81V>B8:0<8 3@C?8 5D5:B@><VF8=C ?>@V7=O=> :V=D5@5=FVW
<10=8, C @57C;LB0B0 G>3> 4VO =530B82=8E 28@V2. ?@5?0@0B <0T ?@>B83@81:>2V AB;=V :5>;>3VW
V=48:0FV9 7 2848 45@<0B>7V2 @V7=>3> ?>E>465==O. V<0DC:>@B 7 <5HCT ABV9:8 4> =0B0

$0@<0:>:>:V=5B8:0.
1A>@1FVO
0B0 =5 01A>@1CT<8 G5@57 =5CH:>465=C H:V@C B0 A;87>2V >1>;>=:8. >6;820 =57=0G=0 :V;L:VABL
01A>@1FVW =5>465=C H:V@C, @>0=8 B0 2849E>40. '5@57 =5CH:>465=C H:V@C 01A>@1FVO
?@@81;87=> 1-3 % 3V4@@>:>@B87>=C; ?@8 5;L:>:>@B87>=C, I> 01A>@1FVO, 71V;LHCT@@@B0A0
242VGV, ?@8 V=D5:FV9=8E C@065==O= H:V@8 C 7 @072V. # 4VB59 01A>@1FVO 01A>@1FVW 7
<5HCT@@@B0A0 7 28>:>

;V=V:V V E0@0:B5@8AB8:8.
>:070==O. >@>B>A0;V ;V:C20==O ?>25@E=52E 45@<0B>7V2, I> ?V4420N@@B0A0, I> ?V2440=0B0=B81V>B8:V2
:><1V=>20=V B5@0?VW 7 0=B81V>B8:V2, I> 71V;LHCT@@@C, B@810< 10:B5@V0;L=>W B0 3@81:>2>W
V=D5:FVN (>A>1;82> A?@8G8=5=V 3@810<8 @>4C *Candida*) GCB;828<8 4> =5>

@>B8?>:070==O.
V4G8B;82VABL 4> :><1V=>20=>3> ?@5?0@0B® :><1V=>20=V (:><1V=>20=8< A:;04>< 4VW), VA=CNBL =0BC@0;V
?@>B8?>:070==O:
- 70E2>@N20==O H:V@8, A?@8G8=5=V ?5@28G=8< 10:B5@V0;L=8< V=D5:FV>><8; ?5@28G=8< <8:>B8G=8< V=D5:FV>><8 (2:;NG0NG8 :0=484>7 B0 48@<0B><V:>7 H:V@8);
- 2V@CA=V V=D5:FVW;
- H:V@=V ?@>O28 B0 @50:FVW ?VA;O 2V:F8=0FVW, ?VA;O 2V:F8=0FVW, ?@V8:8;
- ?>1VG=V @50:FVW, A?@8G8=5=V :><1V=>20=VW< A:;04>< (?5@2V@40 :89:5=89 45@<0B@B0A0, 018@>W);
- V=D5:FV9, @57V;L=89 ?@O28 45@<0B@>7 728G09=> (acne vulgaris), @>7F50, ;8 2>==OA05=5 0:@V7 H:V@8, 01@>@>82> H:V@8.

V<0DC:>@B® =5 A;V4 70AB>A>2C20B8 C 7>2=VH=V9 A;CE>289 :0=0; ?@8 ?5@D>@0FVW
10@010==>W ?5@5B8=:8.

:@V< B>3>, V<0DC:>@B® =5 A;V4 70AB>A>2C20B8 C @07V 3V?5@GCB;82>ABV 4> =5> 03;V:>784V2
01> :>@B8:>>AB5@>W4V2 (I> B@0?;OTBLAO 4C65 @V4:>), G8 4> 1C4L-O:8E 4>?>28=.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9. 0=V ?@> ;V:0@AL:C 270T
<>4VN V<0DC:>@BC®@2V4ACB=V.

A>1;82>ABV 70AB>AC20==O.
878: 28=8:=5==O 1VG=8E @50:FV9 7@>AB0T ?@8 71V;LH5==V B@820>;>ABV ;V:C20==O.
8:>@8AB0==O >:;N7V9=>=>W ?>2O7:8 (F5;>D0=>=2>W) 01> 70AB>AC20==O C 4V;O=FV H:V@@@=8E A:;04>:
71V;LHCT B@0=89 @878:.
(:V@@0 >1;8GGO, 2>;>A8AB>W 4V;O=:8 H:V@@8 3>;>2@28 B0 35=V;B0;V9 T >A>1;82> GCB;82>N 4>
28=8:=5==O
0AB>>AC20==O ?@5?0@0@0BC 2 4V;O=FV >1;8GGO, 738=0GV20 B0 V=H8E 4V;O=>:0E B>=:C>W H:V@@<>65
?@@872520AB88 4> 0B@@>DVW H:V@@8 B0 ?V428I5==O 2A<>:BV20==O ?@5?0@0@0BC.
>@B8:>:>0AB5@@>W48 4;O 3> 70AB>@AC20==O <>6CBL 1CB8 =5157?5G=8<8 C ?@>DVT=BVBV2 7 ?A>@@@V07><
2=0A;V4>: @@@>4C8C @0B5=89=0N870AC9==O H:V@@8 B0 ?V428I5==O 2A@<>:BV20==O ?@5?0@0@0BC.
>@B8:>0AB5@@>W48 4;O 3> 70AB>@AC20==O <>6CBL 1CB8 =5157?5G=8<8 C ?@>DVT=BVBV2 7 ?A>@@@V07><
2=0A;V4>:

70AB>AC20==O 3;N:>:>@B8:>AB5@>W4V2 C ;N48=8 C ?5@V>4 203VB=>ABV, =5>1EV4=>
2@0E>2C20B8 WE=T W 0:B82=>ABV (B0 :;0A), B0:V O: 3V4@:>:>@B87>=, <>6=0 70AB>A>2C20B8
:>@@>B:8<8 :C@A0<8 =0 >1<565=8E 4V;O=:>:0E H:V@@8. ?8A0==V 28I5 5D5:B8 =5 <>6=0 28:;;NG8B8 ?@8
B@@820;;>AC20==V 01> =0=5A5==V =0 25;8:V ?>25@E=V ?>H:>465=>W H:V@@8.
V<0DC:>@B <>6=0 70AB>A>2C20B8 C ?5@V>4 203VB=>ABV :>@@>B:8<8 :C@A0<8 =0 =525;8:8:8E
4V;O=:>:0E H:V@@8. "@820;;5 70AB>AC20==O 01> =0=5A5==O =0 25;8:V 4V;O=::8 ?>H:>465=>W H:V@@8
<>6;82V BV;;L:8 C :@09=VE 28?04:0:E.
>4C20==O 3@C44N.

V4ACB=O V=D>@@0<0FVO ?@@ <>6;82C A5:@5FVN =0B0
V<0DC:>@B :>@@B® <>6=0 70AB>A>2C20B8 C ?5@V>4 43>4C20==O 3@C44N :>@@:>@B:8<8 :C@A0<8 =0
=525;8:8:8E 4V;O=::0E H:V@@8. @8 B@@820;L;@:>@AC20==V 01> =0=5A5==V =0 25;8:V 4V;O=::8 ?>H:>465=>W
H:V@@8 3@4C20==O 3@C44N =5 @5:><5=4CTBLAO.

*40B=VABL 2?;;820B8 =0 H284:VABL @50:FVW ?@@8 :5@C20==V 02B>B@0=A?>@B><= 01> V=H8<<8
<5E0=V7<0<8.*
V4ACB=V 40=V I>4> 2?;;82C ;V:0@AL:>3> 70A>1C V<0DC:>@B® =0 740B=VABL :5@C20B8
02B>B@0=A?>@B><= 01> <5E0=V7<0<8, B0 28=8:=5==O B0:>3> 2?;;82C =5 ?5@54410G0TBLAO.

!?>AV1 70AB>A>2C20==O B0 4>78.
@5?0@0B =0=>A8B8 B>=:8< H0@><= =0 065=V 4V;O=::8 H:V@@8 2-4 @078 =0 4>1C. "@820;V;VABL
:C@AC ;V:C20==O 287>0G0T V=482V4C0;L;=> ;V:0@>= 70;56=> 2V4 E@0:0:B5@C 70E2>@N20==O. C@0
;V:C20==O, O: ?@@028;:>, =5 <0T ?5@528I;8I20B8 14 4=V2.
V<0DC:>@B® C 40=V9 ;V:0@AL:V9 D>@@<V =70 70E2>@N20==L H:V@@8, ?@@8 O:8E 28=8:0NBL
C@@065==O, I> AC?@>2>46CNBLAO AC5VAB8 H:V@@8, CB2>@5==O< ;0AB>28==O B0 B@VI8=.

VB8. @5?0@0B 70AB>A>2CNBLAO 4VB@O< 2V:>< 2V4 1 @:>:C, ?@@4 =03;O4>< ;V:0@O.

5@54>7C20==O. 0=8E I>4> 28?04:V2 ?5@54>7C20==O =5<0T. B5>@5B8G=0 <>6;82VABL
>B@8<0BL8 A8G=>W 4VW =50;5=2=VH=L@3> A;CE2>23> ?@@>E4C =0@02=>2;5 ?@8 =0412@= =0@02O<8
10@01@C==>W ?@5@B8 B0 ?@@><<>CW 4VW =5. >:@5@8<0:5=V 28?04:0:E @@8 28?04::>2 2W C?@0>:28
;V:0@AL:>3> 70A>1C V<0DC:>@B® V<>2V@@=0 ?5@5>A827288B8:C B@>A8G==8E 5D5:BV2.

>1VG==V @50:FVW @5?0@0B.
V4:> (>0,01%, <0,1 %)
1>:C 54==:>:@@8==>W A8AB5<8<.
4@5=>:>:>@B8:>;=0 AC?@5AV<O 2=0;;V4:>: 70AB>A>2C20==O ?@5@8:?@@8;0BV2, I> @8:=05@;N48,
@V:> A@?B0;N30TBLAO C 4@@>A;8E, V =5 ?5@5@410G0TBLAO, I> 2>=0 <>65 28:;8:88 CB2>@@5==O
A8AB5@@8< AC?@5AVW =0@02=V9 :>@B8;5 V<0DC:>@B®. >6;82VABL 2>@@O8@5==L A8AB5@@<:5 5D5:BV2
71V;LH:CTBLAO ?@@8 28:>@@8AB0==V >;N@7V9=>:>W ?@@?>2O87:8, =0=5A5==V =0 25;8:V ?>25@E=V H:V@@8,
?@@8 70AB>A>2C20==V ?@@4B@8>3< 7@8;8O@V9, C >AVB, 0 B0:>6 C 4VB59.
1>:C H:V@@8 B0 ?V4H:V@@=>W :;VB::>28=8.
@8 70AB>A>2C20==V ;V:0@AL:>3> 70A>1C V<0DC:>@B® A@?>65 28:;88 CB2>@@5==O =57@=0G=:>3>
703>@AB@5==O 7 1>:C H:V@@8. &5 =5 ?@@B@@851CT ?@@8?8=5==O ;V:C20==O.
   · @50:FVW 3V?5@GCB;82>ABV, ?5@2N==O B0 ?>4@07078B5==O H:V@@8, 45@<0B8B, 5:75<0,
     :?>B=5==0 89 45@<0B8B;
   · :?>=0B=V 0;5@3V9=V @50:FVW @5?0@0B, >A>1;82> =0 =5>
   · <>6;82V 28;88 CB2>@@5==O 0@BC?=V9 ?>@1VG=V 5D5:B8 :>>@@?>2>B8, 0;5 WE
     2V>@:>3V4=O 2V20;L;VABL ?@@4 70AB>A>2C20==V 3V4@@:>@B87>=C =86G0, =5>B 28:;8:0NBL ?@@4
     70AB>A>2C20==V :>@@B8:>:>@B5@>W4V2 1V;LH 28A>::>W 0:B82:=>ABV:
       - 0B@>>?DV9 H:V@@8, G0AB> =5>5;@@>:>@B;0, V> AC?@@>2>46CTBLAO< H:V@@8,
         B5;50=:>3V>:B>2V>:8, ?C?V0@@?V>@N B0 0B@@>8O<8;
       - @>70F50?>4V;289 B0 ?@@8:O>@0;289 45@@:>0<8:=0, V> AC?@@>2>46CTBLAO 01> =5
         AC?@@>2>46CTBLAO 0B@@>8VN H:V@@8;
       - 5D5:B «@8:0>H5@:>», V> <>65 A@8:0:2B878 AB5@AL:>3> 4=0 70;56=0=V9;
       - C@B=:0B=L:5A 5 703>@N20==O @0>=;

- 45?V3<5=B0FVO, 3V?5@B@8E>7.
878: 28=8:=5==O 1VG=8E @50:FV9 7@>AB0T ?@8 71V;LH5==V B@820;>ABV ;V:C20==O.
8:>@8AB0==O >:;N7V9=>W ?>2O7:8 (F5;>D0=>2>W) 01> 70AB>AC20==O C 4V;O=FV H:V@=8E A.;04>:
71V;LHCT B0:89 @878:. (:V@0 >1;8GGO, 2>;>A8AB>W 4V;O=:8 H:V@@8 3>;>28 B0 35=VB0;V9 T
>A>1;82> GCB;82>N 4> 28=8:=5==O
@8 =52V4?>2V4=>=AC20==V 10:B5@V0;;=V, ?0@078B0@=V, 3@81:>>2V B0 2V@CA=V V=D5:FVW
<>6CBL <0A:C20B8AO B0/01> 703>AB@N20B8AO.
C65 @V4:> (< 0,01 %)
1>:C >@30=V2 7@@@@C: ?V428I5==O 2=CB@V>G=>3>=>3> B8A:A:, 71V;LH5==O @878:C @>728B:C
:0B0@0:B8.
'0AB>B0 =52V4><0
1>:C H:V@0 B0 ?V4H:V@=>W :;VB:8=8: H:V@0=V 28A8?0==O, A25@@1V6 ?:ABC;L>7=5 0>:=5.
878: A8AB5<=<=8E 5D5:BV2 ?V428ICTB;A;AO C =0ABB?=8E 28?04:0E: 70AB>AC20==V 7 28:>@8AB0==O<
?>2O7:8 (F5;>D0=>>20 ?>2O7=>0 01> C 4V;O=:0E H:V@8 A.;04>:); 70AB>AC20==O =0 25;8:8E 4V;O=:0E
H:V@8; 4>23>B@82;0;5 7=0ABO (>4=VV< =04@;0D09B> GCB;82V G5@57 =0@A2=8O2=0B;L C 4V;0H59
B><C H:V@8 B0 2V4=5A=> 25;8:8>W ?;>IV WW ?>25@E=V); =04@;0B8 :8=B5=782 01> 4>?>28=, I>
?>A;;NNB; ?@>=8:=5==O G5@57 @3>;V>3> H00@ B0>01> ?@>A8;NNB 5D5:B >C25==G>W @5G>28=8.
878: @>728B:C 1VG=8E @50:FV9 71V;LHCTBLAO 7V 7@>AB0==O< A8;8 4VW ?@@?0@0B8 B0
B@820;>ABV ;V:C20==O. 0AB>AC20==O V7 28:>@8AB0==O< ?>2O7:8 (F5;>D0=>>20 ?>2O7=>0 01>
=0=0A5A5==O C 4V;O=:0E H:V@8 A.;04>:) ?V428ICT F59 @878:. (:V@0 >1;8GGO B0 2>;>A8AB>W
4V;O=:8 3>;>28, 0 B0:>6 35=VB0;V9, >A>1;82> GCB;82V 4> 28=8:=5==O ?>1VG=8E @50:FV9. @8
=52V4?>2V4=>=AC20==V, 0 B0:>6 ?@8 =04;0B>>=52V4 10:B5@V0;L=8E, ?0@078B0@=8E, 3@81:>2V
2V@CA=8E V=D5:FV9 ?><>6CBL <0A:C20B8AO B0/01> ?>A>;N20B8AO.

"5@ABV. 5 @>:V2.

#<>28 715@V30==O.   15@V30B8 ?@8 B5
15@V30B8 C =54>AB0?=><C

#?0:>2:0. > 15 3 <07V 2 BC1V; ?> 1 BC1V 2 :0@B>=>==V9 :>@>1FV.

0B53>@VO 2V4?CA:C. 0 @5F5?B><

8@>1=8:. "5<<;5@ B0;V0 !.@.;., B0;VO.

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A0 20465==O 4VO;L=>ABV. "5<<;5@ B0;VO !.@.;.: V0 V0
45;;5 =40AB@V, 2, 20061, 0@C30B5 (), B0;VO/TemmlerItalia S.r.l.: Via delle Industrie 2, 20061 Carugate (MI), Italy.

0O2=8:. AB5;;0A $0@<0 .@>? ../Astellas Pharma Europe B. V.

VAF57=0E>465==O 70O2=8:0.
!8;L2VCA253, 62, 2333 BE 5945=, V45@;0=48/Sylviusweg, 62, 2333 BE Leiden, the Netherlands.
@54AB02=8FB2> 2 #:@0W=V: 04050, <. 8W2, 2C;. 8<>=5=:0, 13, >@?. 7-, >DVA 41.

28?04:C 28=8:=5==O ?>1VG=8E 5D5:BV2 ?@>A8<> =0?@02;OB8 V=D>@<0FVN 70 04@5A>< 20O2=8:0 2 #:@0W=V
AB5;;0A $0@<0 .@>? . . =0 04@5AC: 04050,